

REPLACEMENT SHEET

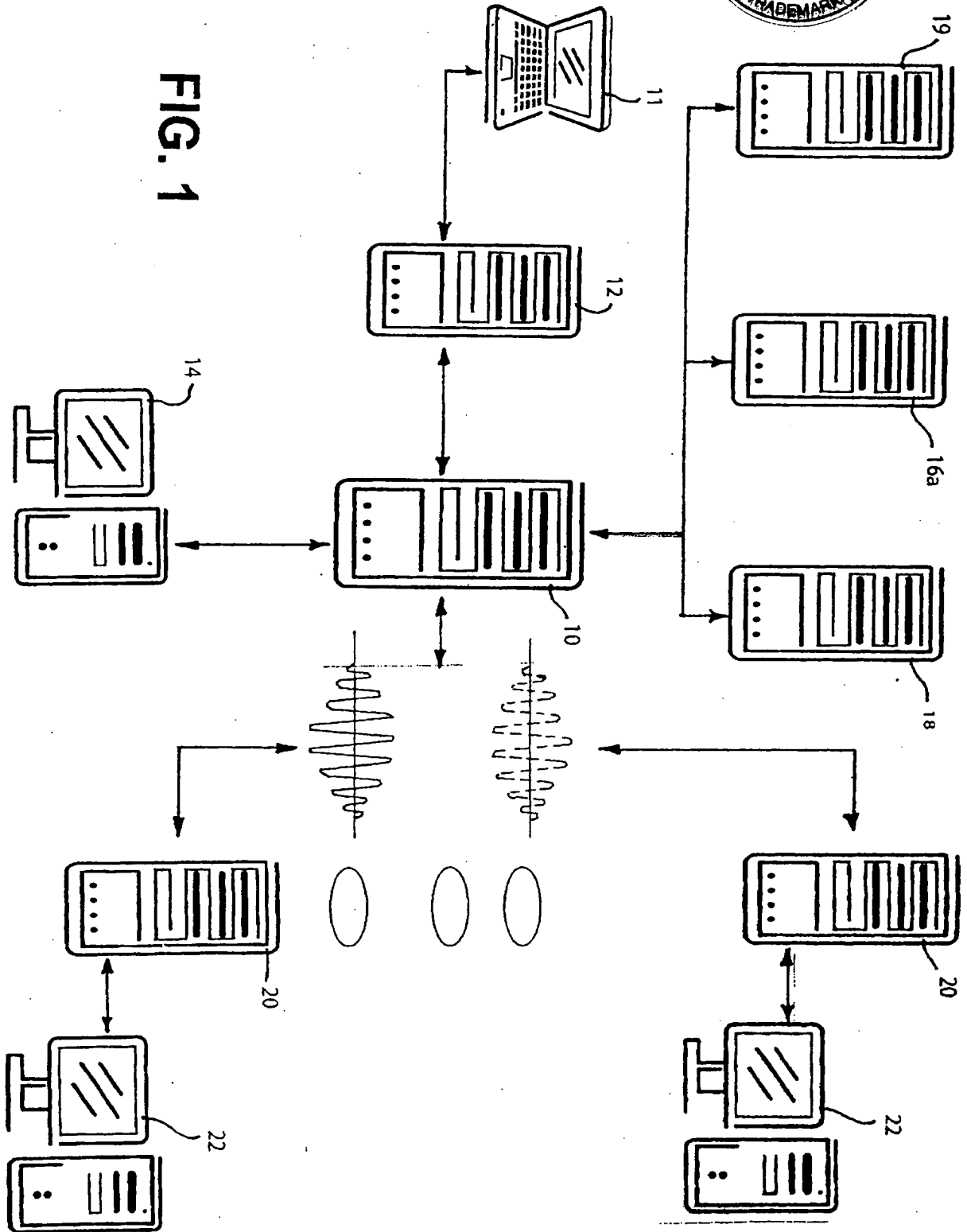


FIG. 2A

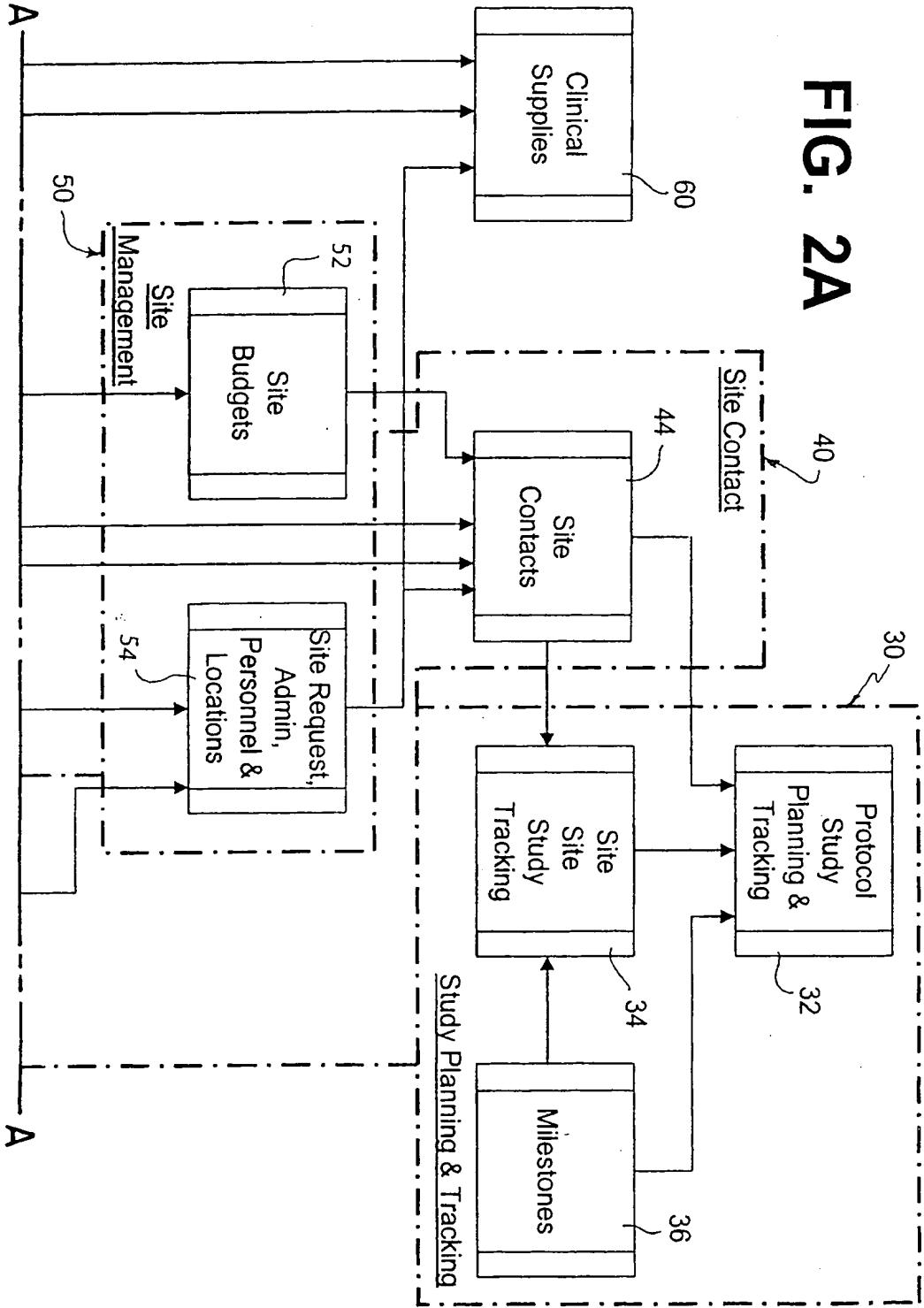
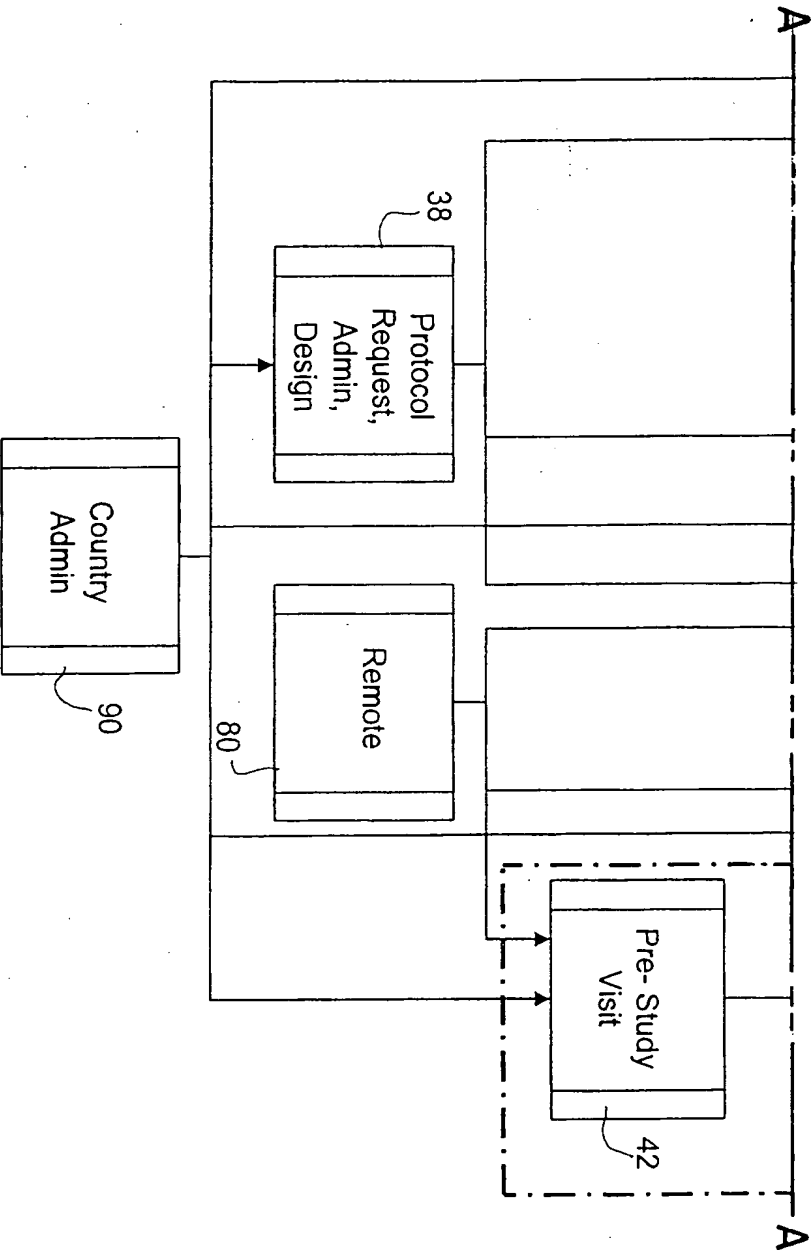


FIG. 2B



REPLACEMENT SHEET

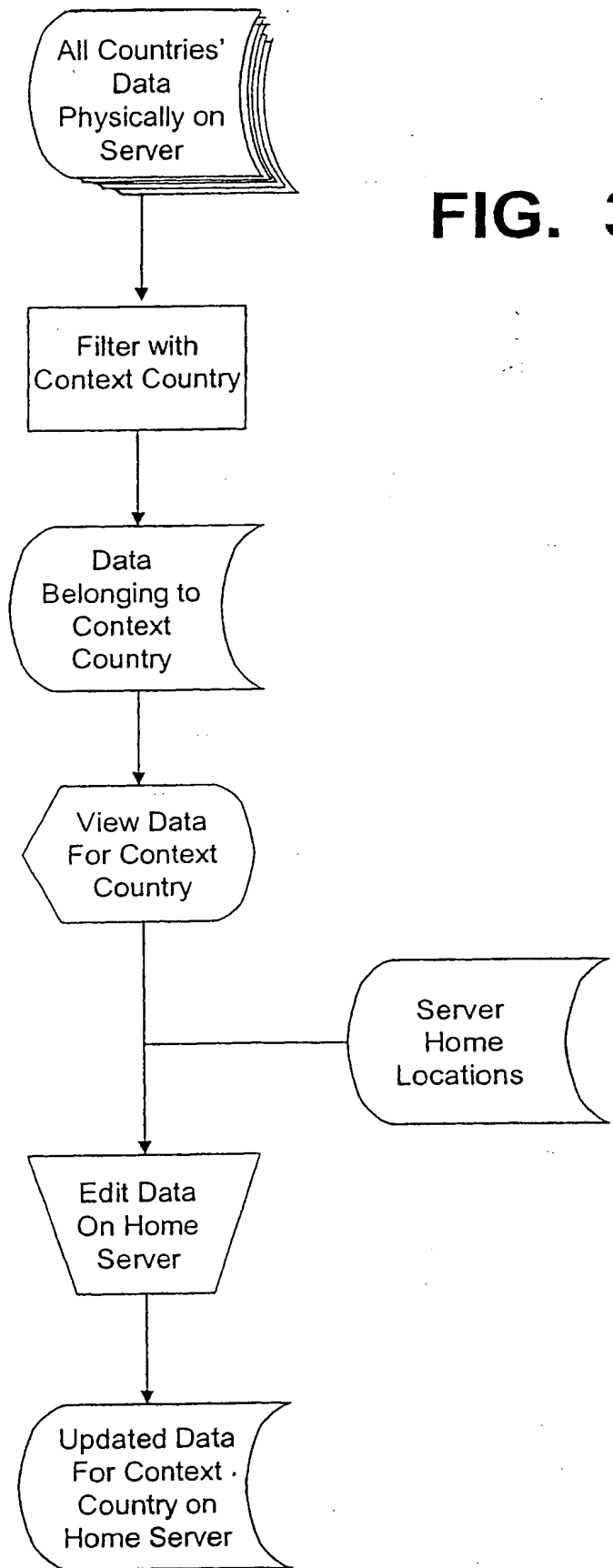


FIG. 3

FIG. 4

PROSIT - Never Never Land									
File	Edit	View	Actions	Modules	Window	Help			
Protocol of Number Req		Protocol		Request		Physician		Protocol Number	Protocol Title
Request ID	Submit Date	Site	Country Administration	Design	Study Planning	Darling, Wendy	-000012	Mometasone vs. Budesonide in Asth	
RQ-0000001	01-MAR-199	Country Administration	Pre-Study Visit	Study Planning	Darling, Wendy	Darling, Wendy	-000065	Mometasone vs. Budesonide in Asth	
RQ-0000002	26-MAR-199	Site Contact	Laptop	Study Tracking	Darling, Wendy	Darling, Wendy		Comparative Study of Topical Cortic	
RQ-0000003	26-MAR-199	Milestones	Clinical Supplies		Medicine, Cheif	Medicine, Cheif		Effects of rHul-10 on Cytochrome P	
RQ-0000004	26-MAR-199				Darling, Wendy	Darling, Wendy		Absorption, Metabolism and Excreti	
RQ-0000005	26-MAR-199				Medicine, Cheif	Medicine, Cheif		Endometrial Histologic Effects of Or	
RQ-0000006	26-MAR-199				Medicine, Cheif	Medicine, Cheif		Comparison of Mometasone Furoste	
RQ-0000007	26-MAR-199				Medicine, Cheif	Medicine, Cheif		Mometasone	
RQ-0000010	31-MAR-199				Medicine, Cheif	Medicine, Cheif	-000112	Comparison of Mometasone Furoste	
RQ-0000079	08-APR-1998	SUBMITTED	Never Never Land	Pan, Peter J	Darling, Wendy	Darling, Wendy		Mometasone	
RQ-0000080	03-APR-1998	ASSIGNED	Never Never Land	Pan, Peter J	Darling, Wendy	Darling, Wendy	-P00008	Mometasone vs. Budesonide in Asth	
RQ-0000103	07-MAY-1998	SUBMITTED	Never Never Land	Pan, Peter J	Darling, Wendy	Darling, Wendy		nge ipgo3ikop3	

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PROSIT - UNITED STATES	
Protocol Number Request Details [New]	
Request No:	Submit Date: Status: NEW
Schering No:	<input type="text"/> Schering Name:
Requester:	Rispoli, Marc C <input type="text"/> SPRI US IND: <input type="text"/>
Project Physician:	<input type="text"/> International: <input type="text"/>
Program:	<input type="text"/>
MktId. Dose Form:	<input type="text"/>
Project Accounting Code: --	<input type="text"/>
Monitoring Area:	<input type="text"/>
Expense Center:	1477-RESEARCH SYS <input type="text"/>
Phase:	<input type="text"/>
Protocol Type:	<input type="text"/>
Working Title:	<input type="text"/>

FIG. 5

FIG. 6

PROSIT - UNITED STATES	
Protocol Administration: I-P00324	
Protocol: I-P00324 Schering No: 000049 Schering Name: ANTERON	
Working Title: testing the new Prosit build version 1.04	
Administration Personnel External Organizations	
Protocol Status	
Protocol Status: Amendment in Progress Study Status: PLANNED Active: <input checked="" type="checkbox"/>	
Finalize Date: 04-NOV-1998 Notification: <input type="checkbox"/> Notif. Date: <input type="checkbox"/>	
Notif. Reason: <input type="checkbox"/>	
Administration/Accounting	
Therapeutic Team: <input type="checkbox"/> Expense Center: 1477-RESEARCH SYS	
Program: INTERNATIONAL ALLERGY Mkt'd. Dose Form: ALKM SRINJ	
Project Acct. Code: F01-000049-303E Originating Sub: United States	
Monitoring Area: MEDICAL AND SCIENTIFIC AFFAIRS Amend. Version: 1 Event Manager: <input checked="" type="checkbox"/>	
Protocol Type: I-MEDICAL RESEARCH INTERNATIO Final Amend. Date: <input type="checkbox"/>	

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PROSIT - Never Never Land	
Employee [View]	
Employee ID: <input type="text"/>	First Name: <input type="text"/> M.I. <input type="checkbox"/>
Last Name: <input type="text"/>	Title: <input type="text"/>
Gender: <input type="text"/>	
Country: <input type="text"/>	
Contact Inform: <input type="text"/>	
Phone No: <input type="text"/>	Fax No: <input type="text"/>
E-Mail Addr: <input type="text"/>	Mail Stop: <input type="text"/>
Expense Center: <input type="text"/>	Type: <input type="text"/>
	Physician: <input type="checkbox"/>

FIG. 7

FIG. 8

PROSIT – Never Never Land									
Protocol Design 000065									
Protocol:		-000065	Schering No. 032088		Schering Name: MOMETASONE				
Working Title: Mometasone vs. Budesonide in Asthma									
Design	Medication	Visit Map	Procedures	Optional Fields	Subject Eligibility	Study Objectives			
Working Title: Mometasone vs. Budesonide in Asthma									
Protocol Title: Efficacy and safety of mometasone furoate dry powder and budesonide powder (pulmicort turbuhaler) in the treatment of asthma									
Primary Indication:		493	Asthma						
IND/HA Ref No:			Phase:		Phase III				
Study Population:		Adults							
Data Collection Tool:		CRF							
Synopsis:									
Salbutamol MDI acceptable for reversibility									
Secondary Indications:		<div>4930</div> <div>EXTRINSIC ASTHMA</div> <div>4931</div> <div>INTRINSIC ASTHMA</div>							

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PROSIT – Never Never Land																													
Protocol Design: -000065																													
Protocol: -000065 Schering No. 032088 Schering Name: MOMETASONE Working Title: Mometasone vs. Budesonide in Asthma																													
Design	Medication	Visit Map	Procedures	Optional Fields	Subject Eligibility	Study Objectives																							
Test Drug Number Test Drug name Role Amendment																													
032088		MOMETASONE		PRIMARY																									
Test drug number can not be modified once saved, to change a test drug number delete it and re add it.																													
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 20%;">Strength</th> <th style="width: 20%;">Regimen</th> <th style="width: 20%;">Dose Form</th> <th style="width: 20%;">Route</th> <th style="width: 20%;">Amendment ID</th> </tr> </thead> <tbody> <tr> <td style="padding: 2px;">100mcg</td> <td style="padding: 2px;">2x daily</td> <td style="padding: 2px;">INHAL PWD</td> <td style="padding: 2px;">INTRANASAL</td> <td style="padding: 2px;"></td> </tr> <tr> <td style="padding: 2px;">200mcg</td> <td style="padding: 2px;">2 an 4x daily</td> <td style="padding: 2px;">INHAL PWD</td> <td style="padding: 2px;">INTRANASAL</td> <td style="padding: 2px;"></td> </tr> <tr> <td style="padding: 2px;"></td> <td style="padding: 2px;"></td> <td style="padding: 2px;"></td> <td style="padding: 2px;"></td> <td style="padding: 2px;"></td> </tr> </tbody> </table>										Strength	Regimen	Dose Form	Route	Amendment ID	100mcg	2x daily	INHAL PWD	INTRANASAL		200mcg	2 an 4x daily	INHAL PWD	INTRANASAL						
Strength	Regimen	Dose Form	Route	Amendment ID																									
100mcg	2x daily	INHAL PWD	INTRANASAL																										
200mcg	2 an 4x daily	INHAL PWD	INTRANASAL																										
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 80%; height: 20px;"></td> <td style="width: 20%;"></td> </tr> </table>																													

FIG. 9

FIG. 10

REPLACEMENT SHEET

PROSIT – Never Never Land									
Protocol Design 000065									
Protocol: <input type="text" value="-000065"/> Schering No. 032088 Schering Name: MOMETASONE Working Title: Mometasone vs. Budesonide in Asthma									
Design	Medication	Visit Map	Procedures	Optional Fields	Subject Eligibility	Study Objectives			
Visit ID	Visit Label	Study Phase	Prev. Visit ID	Days Since Prior Visit Min Max	Enrollment Visit	Amendment ID			
<input type="text" value="1"/>	Test Recruitment	SCREENING	<input type="text" value=""/>	<input type="text" value="0"/> <input type="text" value="0"/>	<input type="checkbox"/>	<input type="checkbox"/>			
<input type="text" value="2"/>	Baseline	TREATMENT	<input type="text" value="1"/>	<input type="text" value="7"/> <input type="text" value="14"/>	<input type="checkbox"/>	<input type="checkbox"/>			
<input type="text" value="3"/>	1st Evaluation	TREATMENT	<input type="text" value="2"/>	<input type="text" value="5"/> <input type="text" value="9"/>	<input type="checkbox"/>	<input type="checkbox"/>			
<input type="text" value="4"/>	2nd Evaluation	TREATMENT	<input type="text" value="3"/>	<input type="text" value="5"/> <input type="text" value="9"/>	<input type="checkbox"/>	<input type="checkbox"/>			
<input type="text" value="5"/>	Final Evaluation	FOLLOW UP	<input type="text" value="4"/>	<input type="text" value="25"/> <input type="text" value="31"/>	<input type="checkbox"/>	<input type="checkbox"/>			
<input type="text" value="6"/>	1st Evaluation Short	TREATMENT	<input type="text" value="5"/>	<input type="text" value="7"/> <input type="text" value="14"/>	<input type="checkbox"/>	<input type="checkbox"/>			
<input type="text" value="7"/>	Final Evaluation Short	FOLLOW UP	<input type="text" value="6"/>	<input type="text" value="25"/> <input type="text" value="31"/>	<input type="checkbox"/>	<input type="checkbox"/>			
<input type="text" value="8"/>			<input type="text" value="7"/>		<input type="checkbox"/>	<input type="checkbox"/>			

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FIG. 11

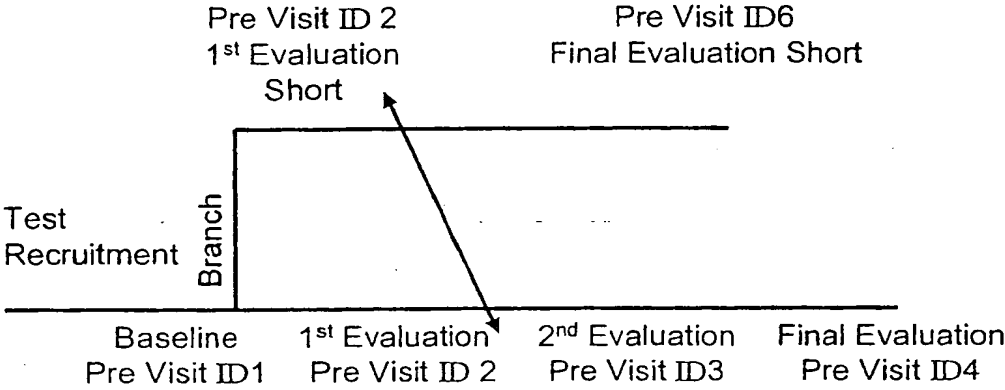


FIG. 13

PROSIT – Never Never Land										
Protocol Design 000065										
Protocol:		-000065	Schering No. 032088		Schering Name: MOMETASONE					
Working Title: Mometasone vs. Budesonide in Asthma										
Design	Medication	Visit Map	Procedures	Optional Fields	Subject Eligibility	Study Objectives				
Subject Optional Field Name			Data Type		Visit Optional Field Name					Date Type
HEIGHT			Decimal		ASTHMA SEVERITY					Integer
AGE ASTHMA ONSET			Integer		TREATMENT RESPONSE CORE					Integer
CONCOMITANT MED WASHOUT			Yes/No							

PROSIT – Never Never Land

FIG. 14

Protocol Design P00008

Protocol: -P-00008

Schering No. 032088

Schering Name: MOMETASONE

Working Title: Mometasone vs. Budesonide in Asthma

Design Medication Visit Map Procedures Optional Fields Subject Eligibility Study Objectives

Reason for Ineligibility

EXCLUDED CONCOMITANT MEDICATION

DID NOT MEET ENTRANCE CRITERIA

SUBJECT DID NOT WISH TO PARTICIPATE

EXCLUDED CONCOMITANT ILLNESS

Reason for Discontinuation

DID NOT MEET ENTRANCE CRITERIA

DISEASE IS NOT SEVERE ENOUGH

DISEASE IS TOO SEVERE

EXCLUDED CONCOMITANT ILLNESS

EXCLUDED CONCOMITANT MEDICATION

HISTORY IS NOT APPROPRIATE FOR ENTRY

RECENT EXCLUDED HOSPITALIZATION OR PROCEDURE

SUBJECT AGE IS NOT APPROPRIATE

SUBJECT DID NOT RETURN FOR SCREENING

SUBJECT DIED PRIOR TO SCREENING

NC
DN
DS
EI
EM
HN
EH
SA
SS
SD

REPLACEMENT SHEET

FIG. 15

PROSIT – Never Never Land									
Protocol Design P000008									
Protocol: <input type="text" value="-P-000008"/> Schering No. 032088 Schering Name: MOMETASONE Working Title: Mometasone vs. Budesonide in Asthma									
Design	Medication	Visit Map	Procedures	Optional Fields	Subject Eligibility	Study Objectives			
Reason for Ineligibility							Reason for Discontinuation		
EXCLUDED CONCOMITANT MEDICATION <input type="checkbox"/>							ADVERSE EVENT <input type="checkbox"/>		
PREGNANCY <input type="checkbox"/>							PRE-ATRO <input type="checkbox"/>		
DISEASE IS TOO SEVERE <input type="checkbox"/>							TREATMENT FAILURE, DX STATUS MOD/SEVERE <input type="checkbox"/>		
<input type="checkbox"/>							LOST TO FOLLOWUP <input type="checkbox"/>		
<input type="checkbox"/>							INVESTIGATOR DEEMS NOT IN SUBJECTS INTEREST <input type="checkbox"/>		
<input type="checkbox"/>							NON-COMPLIANCE <input type="checkbox"/>		
<input type="checkbox"/>							DID NOT MEET PROTOCOL ELIGIBILITY <input type="checkbox"/>		
ADMINISTRATIVE							70		
ADVERSE EVENT							10		
CLEARED							80		
COMPLETE							00		
DEATH							99		
DID NOT ENTER NEXT PHASE							51		
DID NOT MEET CROSSOVER REQUIREMENTS							64		
DID NOT MEET PROTOCOL ELIGIBILITY							60		
DID NOT MEET PROTOCOL REQUIREMENTS							63		
DID NOT MEET RANDOMIZATION CRITERIA							65		

FIG. 16

PROSIT - Never Never Land					
Protocol Design P00008					
Protocol: <input type="text" value="-P-00008"/> Schering No. 032088 Schering Name: MOMETASONE Working Title: Mometasone vs. Budesonide in Asthma					
Design	Medication	Visit Map	Procedures	Optional Fields	Subject Eligibility Study Objectives
Special Components			Design Considerations		
EFFICACY <input type="text"/>			DOUBLE BLIND <input type="text"/>		
BIOEQUIVALENCY <input type="text"/>			ACTIVE COMPARISON <input type="text"/>		
<input type="text"/>			PARALLEL GROUP <input type="text"/>		
			RANDOMIZED <input type="text"/>		
			FOUR WAY CROSSOVER <input type="text"/>		
			LATIN SQUARE <input type="text"/>		
			NO TREATMENT CONTROL <input type="text"/>		
			OPEN LABEL <input type="text"/>		
PARALLEL GROUP <input type="text"/>			RANDOMIZED <input type="text"/>		
PLACEBO CONTROL <input type="text"/>			SINGLE BLIND <input type="text"/>		
PLACEBO WASHOUT <input type="text"/>			THREE WAY CROSSOVER <input type="text"/>		

REPLACEMENT SHEET

FIG. 17

PROSIT - UNITED STATES				
File	Edit	View	Actions	Modules
			Window	Help
			Refresh	Alt+R
Protocol Admin			Finalize Protocol	
			Amend Protocol	
Protocol: I-P00			Finalize Amendment	g Name: ANTERON
Working Title:			Event Manager	
			Amendment History	
Administration			Personnel	External Organizations

Protocol Status: Finalized		Study Status: Enrollment Ongoing		Active: <input checked="" type="checkbox"/>	
Finalize Date: 12-MAR-1998		Notification:		Notif. Date:	
Notif. Reason:					

Administration/Accounting		Expense Center: 834 Mgt Devel & Planning	
Therapeutic Team: Allergy/Asthma (Allergy)			
Program: LINE EXTENSION ALLERGY		Mkt'd. Dose Form: Oral Powd-GMP	
Project Acct. Code: C01-032088-123G		Originating Sub: United States	
Monitoring Area: MARKETING		Amend. Version: Event Manager: <input checked="" type="checkbox"/>	
Protocol Type: I- MEDICAL RESEARCH DOMESTIC		Final Amend. Date:	

FIG. 18

REPLACEMENT SHEET

PROSIT - UNITED STATES												
Master Task List												
Seq	Task Name	Task Type	Task ID	Milestone								
1	Completion of Clinical Program	SIMPLE	50	✓	<input type="checkbox"/>							
2	Investigator Agreement Sent to HQ	SIMPLE	23	✓	<input type="checkbox"/>							
3	Curriculum Vitae of Principal Investigators(s)	SIMPLE	39	✓	<input type="checkbox"/>							
4	CV of Laboratory Director(s) Received in S	SIMPLE	43	✓	<input type="checkbox"/>							
5	Informed Consent Task (Trans)	SIMPLE	26	✓	<input type="checkbox"/>							
6	Gov. Regulatory App. (w/trans) Received in Sub	SIMPLE	30	✓	<input type="checkbox"/>							
7	CV of Laboratory Director(s) Received in Sub	SIMPLE	34	✓	<input type="checkbox"/>							
8	this is a new master task that was created by mark fung-a-	SIMPLE	439	✓	<input type="checkbox"/>							
9	this is another very long task name that was created on the	SIMPLE	441	✓	<input type="checkbox"/>							
10	Site Administration	SIMPLE	447	✓	<input type="checkbox"/>							
11	Site Administration- Location/Personnel	SIMPLE	448	✓	<input type="checkbox"/>							
12	Site Administration- Personnel and Location	SIMPLE	457	✓	<input type="checkbox"/>							
13	Mark	SIMPLE	482	✓	<input type="checkbox"/>							
14	Site Administration	SIMPLE	499	✓	<input type="checkbox"/>							
15	First Data Discrepancy Report Available	SIMPLE	529	✓	<input type="checkbox"/>							
16	Master Task Comm	SIMPLE	569	✓	<input type="checkbox"/>							
17	First Subject/first Visit (Protocol)	SIMPLE	570	✓	<input type="checkbox"/>							
18	Root	SIMPLE	0	✓	<input type="checkbox"/>							
19	Design Start	SIMPLE	48	✓	<input type="checkbox"/>							
20	Primary Stat Analysis Results Released	SIMPLE	15	✓	<input type="checkbox"/>							
<table border="1"> <thead> <tr> <th>Rollup Task Name</th> <th>Type</th> <th>System ID</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> <td></td> </tr> </tbody> </table>							Rollup Task Name	Type	System ID			
Rollup Task Name	Type	System ID										

FIG. 19

REPLACEMENT SHEET

PROSIT – UNITED STATES				
Core Task List				
Core Task List		Core Site Instructions		
Seq	Name	Task Type Name	Milestone Indicator	
1	Protocol Number Assigned	EVENT MANAGER SIMPLE	✓	
2	Final Protocol Date	EVENT MANAGER SIMPLE	✓	
3	Final CRF / RDE Screens Available	SIMPLE	✓	
4	First Site Initiated	SUMMARY	✓	
5	First Subject Enrolled (Protocol)	SUMMARY	✓	
6	First Subject / First Visit	SUMMARY	✓	
7	Enrollment Cutoff (Protocol)	EVENT MANAGER SIMPLE	✓	
8	Last Subject / Last Visit (Protocol)	EVENT MANAGER SIMPLE	✓	
9	Last CIVE / Data Discrepancy In-house	SIMPLE	✓	
10	Data Cleanup Complete (Protocol)	EVENT MANAGER SIMPLE	✓	
11	Database Locked	EVENT MANAGER SIMPLE	✓	
12	Primary Stat Analysis Results Released	SIMPLE	✓	
13	Final Statistical Results Released	SIMPLE	✓	
14	Final Data Listings Released	SIMPLE	✓	
15	Final PCS Date	SIMPLE	✓	
16	Last Data In-house/SPRI HQ (Protocol)	EVENT MANAGER SIMPLE	✓	
17	Last Site Initiated (to Date)	SUMMARY	✓	
18	(New)			

FIG. 20

REPLACEMENT SHEET

PROSIT - UNITED STATES				
Core Task List				
Core Site Instructions				
Seq	Task Name	Task Type Name	Milestone Indicator	TIA Indicator
24	Prestudy Visit Form(s) Received in Subsidiary	SIMPLE	✓	✓
25	Prestudy Visit Form(s) Sent to HQ	SIMPLE	✓	✓
26	Protocol Signed by Investigator Rec. in Sub.	SIMPLE	✓	✓
27	First Subject Enrolled (Site)	AUTOMATIC ROLL-UP	✓	✓
28	Protocol Signed by Investigator Sent to HQ	SIMPLE	✓	✓
29	Site Initiated	AUTOMATIC ROLL-UP	✓	✓
30	First Subject Screened	AUTOMATIC ROLL-UP	✓	✓
31	All Data In-house (Site)	MANUAL ROLL-UP	✓	✓
32	Written Ethics Committee App. (w/trans) Sent	SIMPLE	✓	✓
33	Written Ethics Committee App. (w/trans) Rec.	SIMPLE	✓	✓
34	Data Clean-up Complete (Site)	MANUAL ROLL-UP	✓	✓
35	Enrollment Complete (Site)	MANUAL ROLL-UP	✓	✓
36	this is a new master task that was created by mark f	SIMPLE	✓	✓
37	New Requirement	SIMPLE	✓	✓
38	Site Administration-Personnel and Location	SIMPLE	✓	✓
39	Site Administration	SIMPLE	✓	✓
40	Site Administration	SIMPLE	✓	✓
41	this is another very long task name that was created	SIMPLE	✓	✓
42	Milestone task added to check the duration	SIMPLE	✓	✓
43	A master task with the milestone indic	SIMPLE	✓	✓

FIG. 21

PROSIT - UNITED STATES									
Template Tab Folder									
Template:		1352	Changed: <input checked="" type="checkbox"/>		Country: UNITED STATES				
Name:		Template to test the milestone indc change							
Template		Site Instructions							

Seq	Task Name	Days	Task Type Name					
1	USA-Template to test the milestone indc change		USER DEFINED	-		<input type="checkbox"/>		
2	Protocol Number Assigned	1	EVENT MANAGERS	-		<input checked="" type="checkbox"/>		
3	Final Protocol Date	0	SIMPLE	<input checked="" type="checkbox"/>		<input type="checkbox"/>		
4	Final CRF / RDE Screen Date	0	SIMPLE	<input checked="" type="checkbox"/>		<input type="checkbox"/>		
5	First Site Initiated	0	SUMMARY	<input checked="" type="checkbox"/>		<input type="checkbox"/>		
6	First Subject / First Visit (Protocol)	0	SIMPLE	<input checked="" type="checkbox"/>		<input type="checkbox"/>		
7	Enrollment Complete (Protocol)	0	EVENT MANAGERS	<input checked="" type="checkbox"/>		<input type="checkbox"/>		
8	Last Subject / Last Visit (Protocol)	0	EVENT MANAGERS	<input checked="" type="checkbox"/>		<input type="checkbox"/>		
9	Data Cleanup Complete (Protocol)	0	EVENT MANAGERS	<input checked="" type="checkbox"/>		<input type="checkbox"/>		
10	Last Data Discrepancy Resolved	0	SIMPLE	<input checked="" type="checkbox"/>		<input type="checkbox"/>		
11	Database Locked	0	EVENT MANAGERS	<input checked="" type="checkbox"/>		<input type="checkbox"/>		
12	Primary Stat Analysis Results Released	0	SIMPLE	<input checked="" type="checkbox"/>		<input type="checkbox"/>		
13	Final Statistical Results Released	0	SIMPLE	<input checked="" type="checkbox"/>		<input type="checkbox"/>		
14	Final Data Listings Released	1	SIMPLE	-		<input type="checkbox"/>		
15	Final PCS Date	0	SIMPLE	<input checked="" type="checkbox"/>		<input type="checkbox"/>		
16	First Subject Enrolled	0	SUMMARY	<input checked="" type="checkbox"/>		<input type="checkbox"/>		
17	First Subject First Visit	0	SUMMARY	<input checked="" type="checkbox"/>		<input type="checkbox"/>		
18	Budget Info. Sheet (signed & dated by Inv.) Rec.	0	SIMPLE	<input checked="" type="checkbox"/>		<input type="checkbox"/>		

REPLACEMENT SHEET

REPLACEMENT SHEET

PROSIT – Never Never Land																			
Study Planning																			
Protocol: A-P00216 Schering No: 032088 Schering Name: MOMETASONE																			
Country: Never Never Land Plan Status: DRAFT Plan Version: 0																			
Protocol Projections	Study Planning	Site Instructions																	
<div>Select a Template</div> <table border="1"><thead><tr><th>Template Name</th><th>Template ID</th></tr></thead><tbody><tr><td>Allergy</td><td>693</td></tr><tr><td>Anti-infectives</td><td>695</td></tr><tr><td>CNS</td><td>697</td></tr><tr><td>Cardiovascular</td><td>696</td></tr><tr><td>Core Task Template</td><td>694</td></tr><tr><td>Dermatology</td><td>698</td></tr><tr><td>Oncology</td><td>699</td></tr></tbody></table> <div>Select Cancel</div>				Template Name	Template ID	Allergy	693	Anti-infectives	695	CNS	697	Cardiovascular	696	Core Task Template	694	Dermatology	698	Oncology	699
Template Name	Template ID																		
Allergy	693																		
Anti-infectives	695																		
CNS	697																		
Cardiovascular	696																		
Core Task Template	694																		
Dermatology	698																		
Oncology	699																		

FIG. 22

REPLACEMENT SHEET

PROSIT – Never Never Land																																								
Study Planning																																								
Protocol: A-P00216		Schering No. 032088																																						
Country: NEVER NEVER LAND		Schering Name: MOMETASONE																																						
Plan Status: DRAFT		Plan Version: 0																																						
<div style="display: flex; justify-content: space-around; width: 100%;"> Protocol Projections Study Planning Site Instructions </div>																																								
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th style="text-align: center;">Planned</th> <th style="text-align: center;">Latest Est.</th> </tr> </thead> <tbody> <tr> <td>Evaluable Subjects</td> <td style="text-align: center;">40</td> <td style="text-align: center;"></td> </tr> <tr> <td>Subjects to Enroll</td> <td style="text-align: center;">50</td> <td style="text-align: center;"></td> </tr> <tr> <td>Sites NEVER NEVER LAND</td> <td style="text-align: center;">2</td> <td style="text-align: center;"></td> </tr> <tr> <td>Sites International</td> <td style="text-align: center;">0</td> <td style="text-align: center;"></td> </tr> <tr> <td>Sites Per Monitor</td> <td style="text-align: center;">2</td> <td style="text-align: center;"></td> </tr> <tr> <td>Sites Per HQ CRA</td> <td style="text-align: center;">0</td> <td style="text-align: center;"></td> </tr> <tr> <td>Monitoring Interval wks</td> <td style="text-align: center;">6</td> <td style="text-align: center;"></td> </tr> <tr> <td>Min No Subjects Per Site</td> <td style="text-align: center;">25</td> <td style="text-align: center;"></td> </tr> <tr> <td>Average Subjects Per Site</td> <td style="text-align: center;">0</td> <td style="text-align: center;"></td> </tr> </tbody> </table>		Planned	Latest Est.	Evaluable Subjects	40		Subjects to Enroll	50		Sites NEVER NEVER LAND	2		Sites International	0		Sites Per Monitor	2		Sites Per HQ CRA	0		Monitoring Interval wks	6		Min No Subjects Per Site	25		Average Subjects Per Site	0		<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Monitoring Countries</th> <th style="text-align: center;">Planned</th> <th style="text-align: center;">Latest Est.</th> </tr> </thead> <tbody> <tr> <td>NEVER NEVER LAND </td> <td style="text-align: center;">0</td> <td style="text-align: center;">0</td> </tr> <tr> <td style="text-align: right;">Totals</td> <td style="text-align: center;">0</td> <td style="text-align: center;">0</td> </tr> </tbody> </table>	Monitoring Countries	Planned	Latest Est.	NEVER NEVER LAND	0	0	Totals	0	0
	Planned	Latest Est.																																						
Evaluable Subjects	40																																							
Subjects to Enroll	50																																							
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Sites International	0																																							
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Average Subjects Per Site	0																																							
Monitoring Countries	Planned	Latest Est.																																						
NEVER NEVER LAND	0	0																																						
Totals	0	0																																						

FIG. 23

FIG. 24

PROSIT - Never Never Land

Study Planning

Protocol: Schering No. 032088 Schering Name: MOMETASONE

Country: Plan Status: Plan Version: 0

Protocol Projections		Study Planning	Site Instructions		Latest			
Seq	Task Name	Latest Date	Actual Date					
1	AP00216 - NNI	18-JUN-1998	18-JUN-1998	0	18-JUN-1998	18-JUN-1999	0	0
2	Protocol Number Assigned	18-JUN-1998	18-JUN-1998	0	18-JUN-1998	18-JUN-1998	0	0
3	Protocol Approved	00-000-0000	00-000-0000	0	00-000-0000	00-000-0000	0	0
4	Investigators Identified	00-000-0000	00-000-0000	1	00-000-0000	00-000-0000	1	0
5	Pre-Study Visits Conducted	00-000-0000	00-000-0000	1	00-000-0000	00-000-0000	1	0
6	Last Pre-Study Visit Report	00-000-0000	00-000-0000	0	00-000-0000	00-000-0000	0	0
7	First Site Initiated	00-000-0000	00-000-0000	0	00-000-0000	00-000-0000	0	0
8	First Subject First Visit	00-000-0000	00-000-0000	0	00-000-0000	00-000-0000	0	0
9	Enrollment Complete (Protocol)	00-000-0000	00-000-0000	0	00-000-0000	00-000-0000	0	0
10	Last Subject / Last Visit (Protoc	00-000-0000	00-000-0000	0	00-000-0000	00-000-0000	0	0
11	All Data In house (Protocol)	00-000-0000	00-000-0000	0	00-000-0008	00-000-0000	0	0
12	Database Locked	00-000-0000	00-000-0000	0	00-000-0000	00-000-0000	0	0
13	Primary Stat Analysis Results	00-000-0000	00-000-0000	0	00-000-0000	00-000-0000	0	0
14	Protocol Analysis Final	00-000-0000	00-000-0000	0	00-000-0000	00-000-0000	0	0
15	CSR Approved	00-000-0000	00-000-0000	0	00-000-0000	00-000-0000	0	0
16	(New)	00-000-0000	00-000-0000	1	00-000-0000	00-000-0000	0	0

REPLACEMENT SHEET

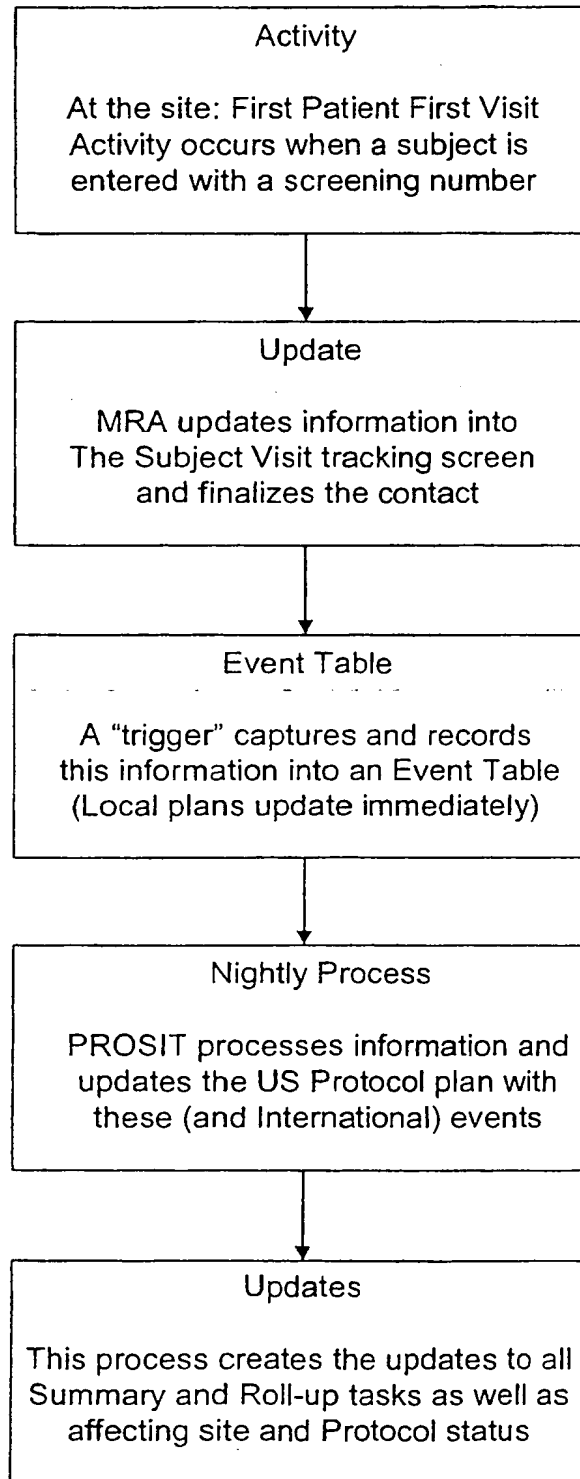
FIG. 25

REPLACEMENT SHEET

PROSIT - Never Never Land									
Study Planning									
Protocol: P-P00124		Schering No. 000105		Schering Name: ESTRADIOL					
Country: NEVER NEVER LAND		Plan Status: DRAFT		Plan Version: 0					
Study Planning		Site Instructions		Protocol Projections		SMP Study Plan		SMP Site Instructions	
Seq	Task Name	Planned Start Dt	Planned End Dt	Planned	Planned Min Delay	Latest Start Dt	Latest End Dt	Latest Days	Latest Min Delay
1	PP00124 - USA	12-AUG-1999	12-AUG-1999	0		12-AUG-1999	12-AUG-1999	0	
2	Protocol Number Assigned	12-AUG-1999	12-AUG-1999	0		12-AUG-1999	12-AUG-1999	0	
3	Final Protocol Date	00-000-0000	00-000-0000	0	0	00-000-0000	00-000-0000	0	0
4	Final CRF/RDI Screens Available	00-000-0000	00-000-0000	1	0	00-000-0000	00-000-0000	1	0
5	First Site Initiated	00-000-0000	00-000-0000	0	0	00-000-0000	00-000-0000	0	0
6	First Subject Enrolled (Protocol)	00-000-0000	00-000-0000	0	0	00-000-0000	00-000-0000	0	0
7	First Subject First Visit	00-000-0000	00-000-0000	0	0	00-000-0000	00-000-0000	0	0
8	Enrollment Cutoff (Protocol)	00-000-0000	00-000-0000	0	0	00-000-0000	00-000-0000	0	0
9	Last Subject/Last Visit (Protocol)	00-000-0000	00-000-0000	0	0	00-000-0000	00-000-0000	0	0
10	Last CIVE/Data Discrepancy InHo	00-000-0000	00-000-0000	0	0	00-000-0000	00-000-0000	0	0
11	Data Cleanup Complete (Protocol)	00-000-0000	00-000-0000	0	0	00-000-0000	00-000-0000	0	0
12	Database Locked	00-000-0000	00-000-0000	0	0	00-000-0000	00-000-0000	0	0
13	Primary Stat Analysis Results Re	00-000-0000	00-000-0000	5	0	00-000-0000	00-000-0000	5	0
14	Final Statistical Results Releas	00-000-0000	00-000-0000	0	0	00-000-0000	00-000-0000	0	0
15	Final Data Listings Released	00-000-0000	00-000-0000	0	0	00-000-0000	00-000-0000	0	0

REPLACEMENT SHEET

FIG. 26



REPLACEMENT SHEET

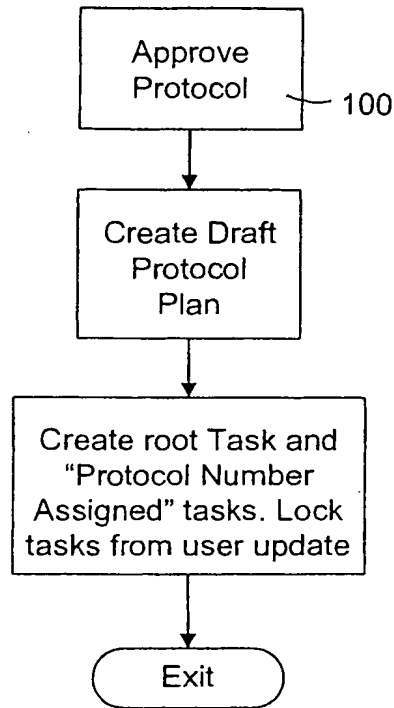


FIG. 27a

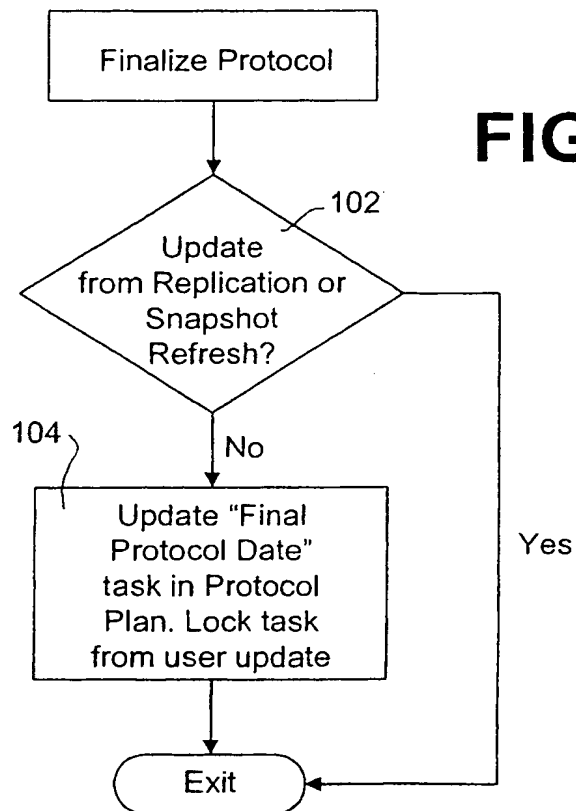
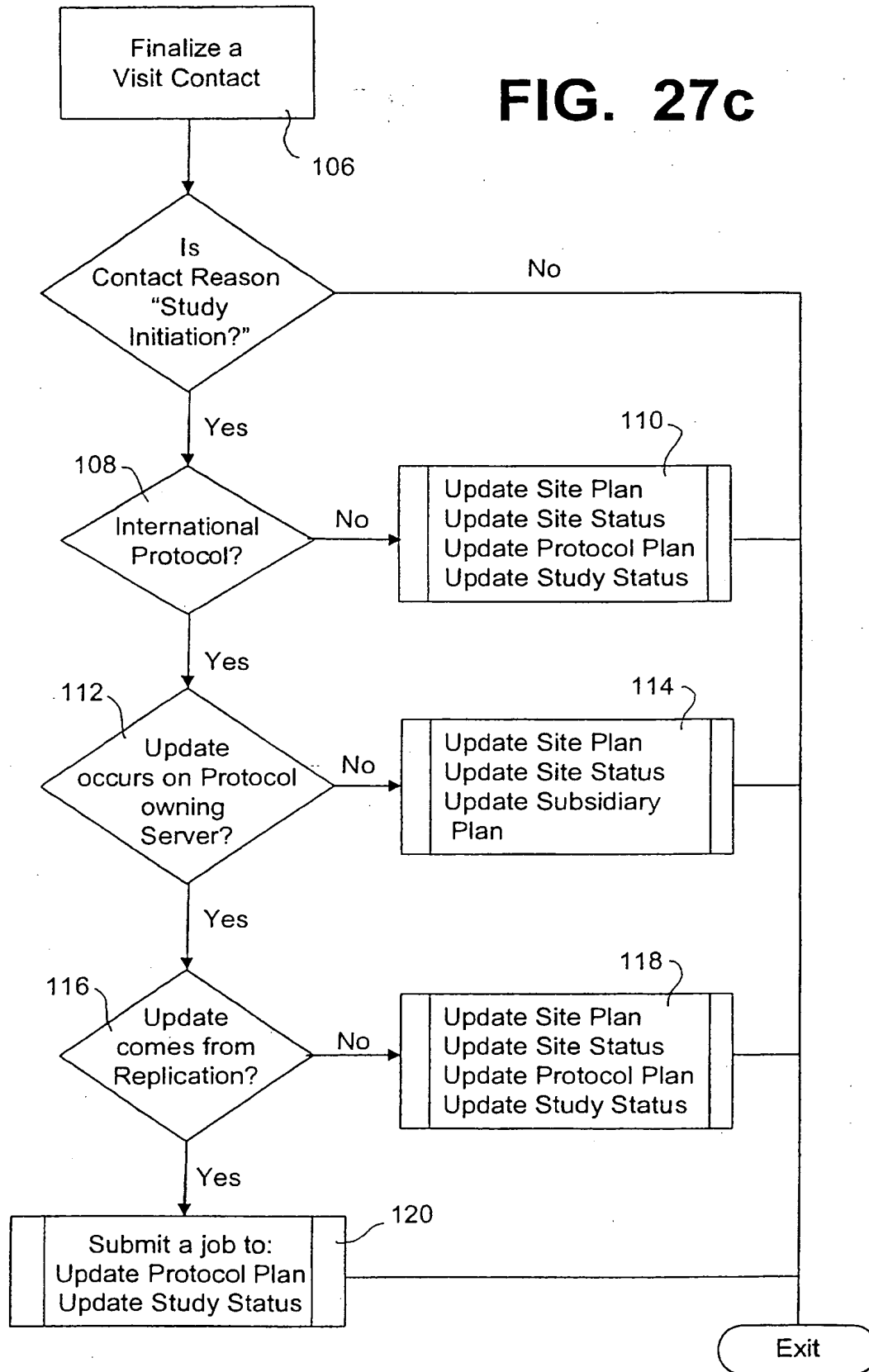


FIG. 27b

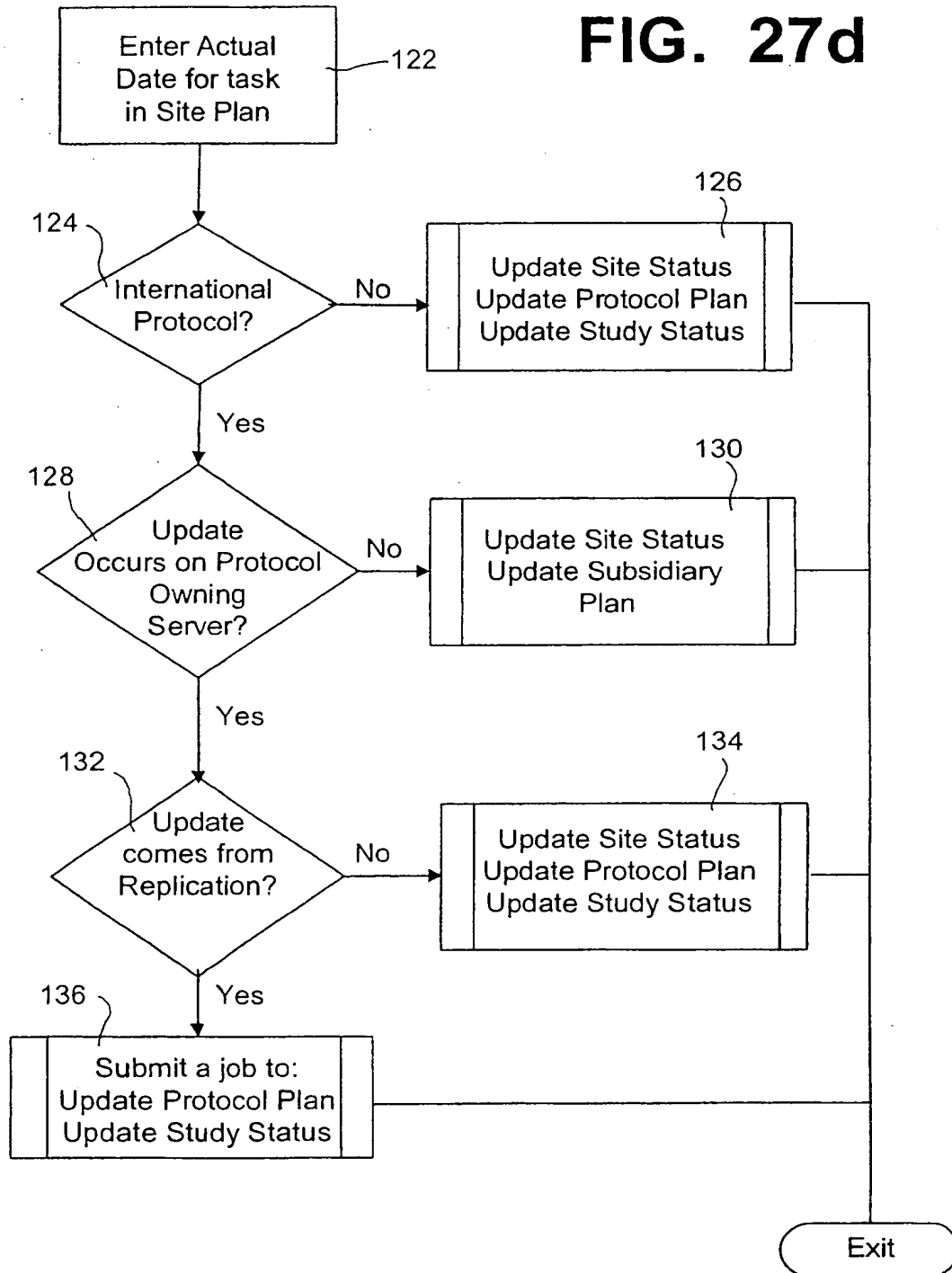
REPLACEMENT SHEET

FIG. 27c



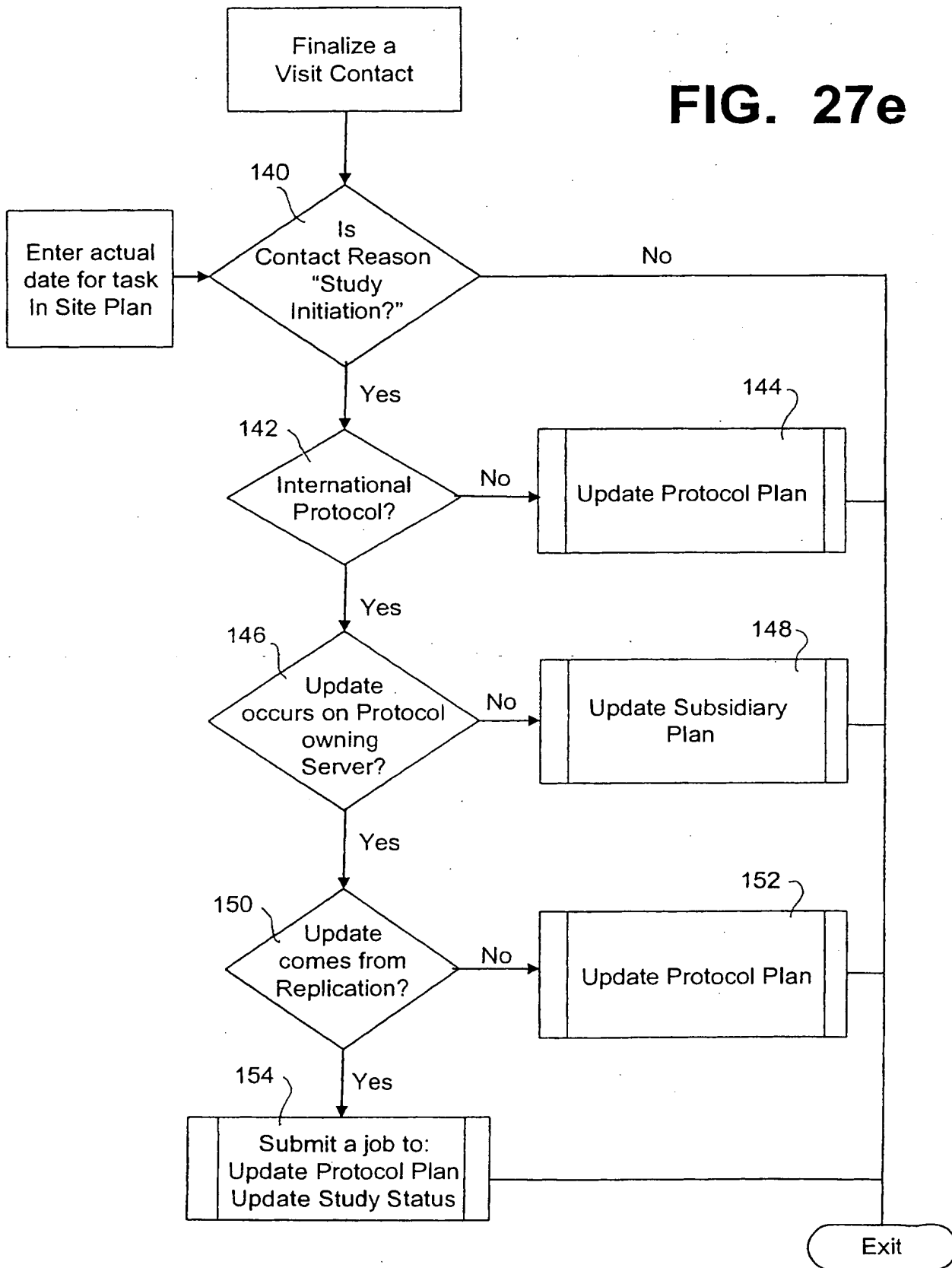
REPLACEMENT SHEET

FIG. 27d



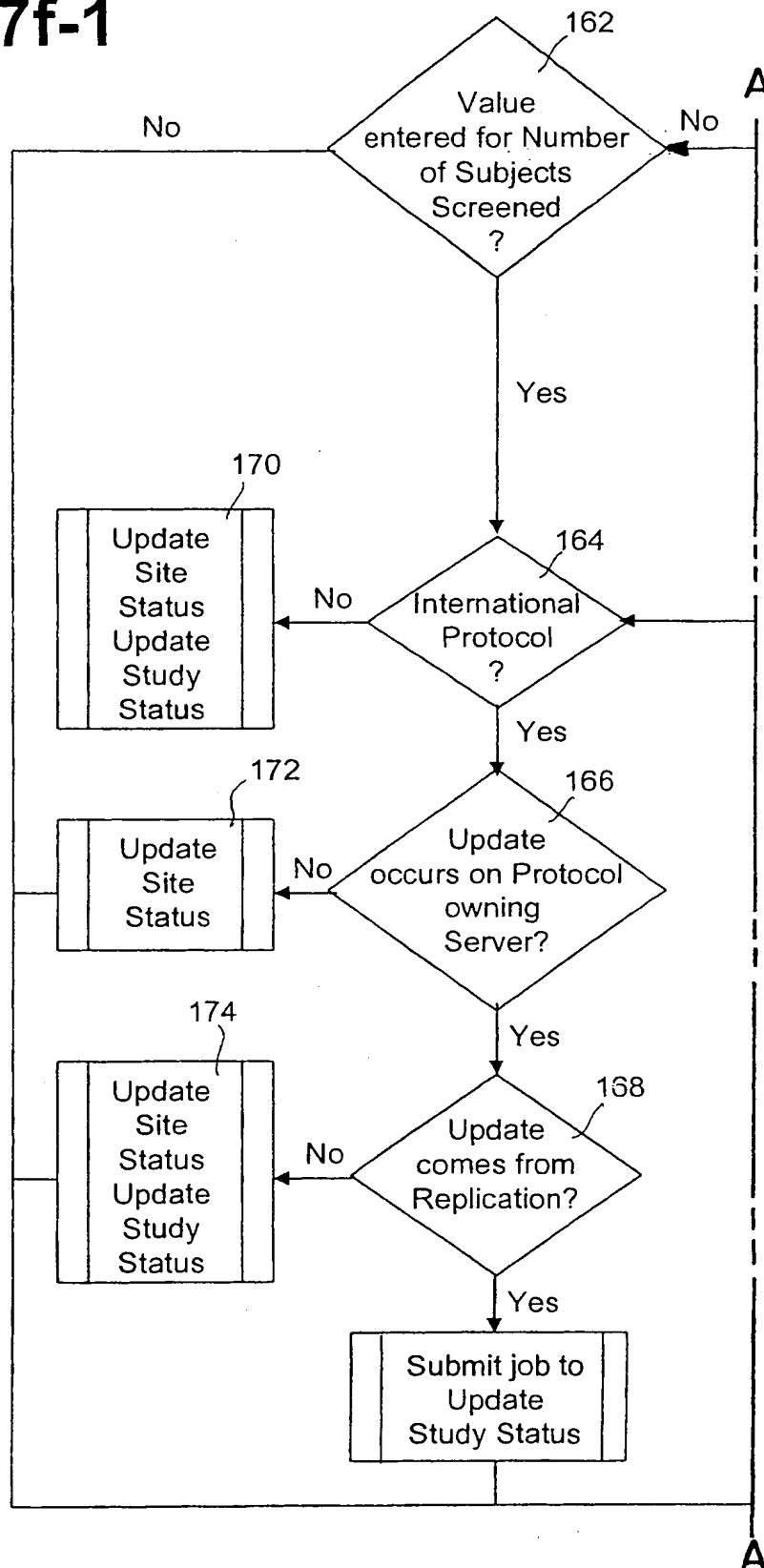
REPLACEMENT SHEET

FIG. 27e



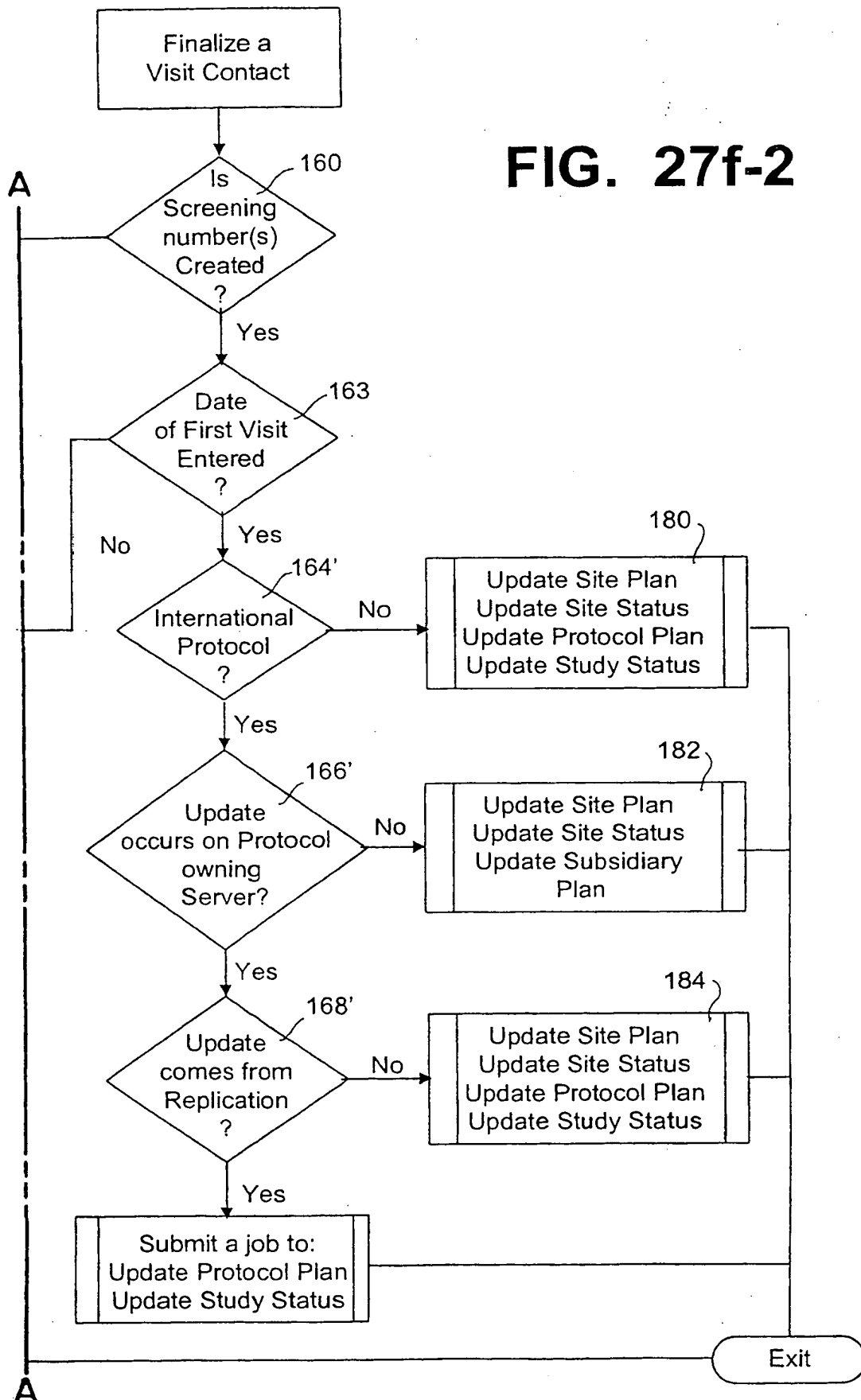
REPLACEMENT SHEET

FIG. 27f-1



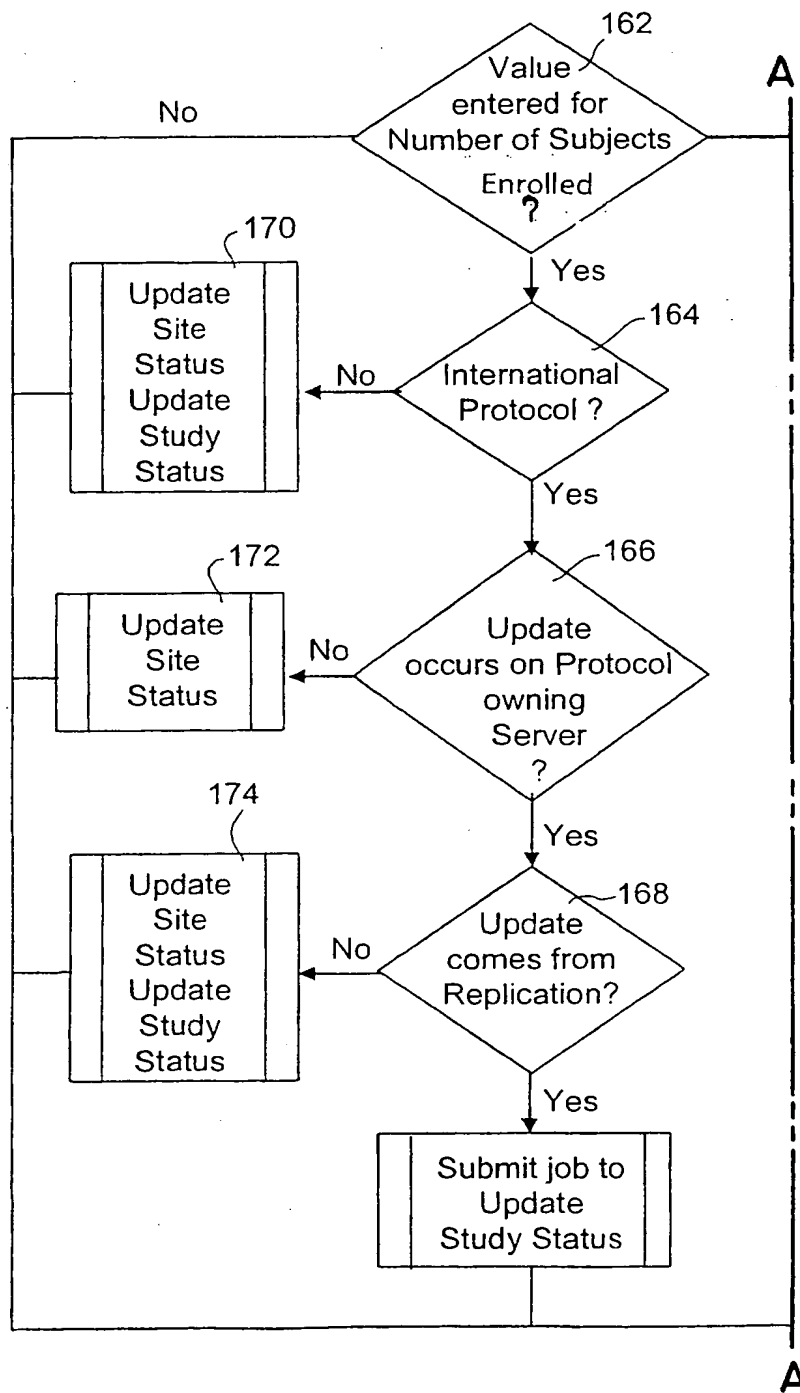
REPLACEMENT SHEET

FIG. 27f-2



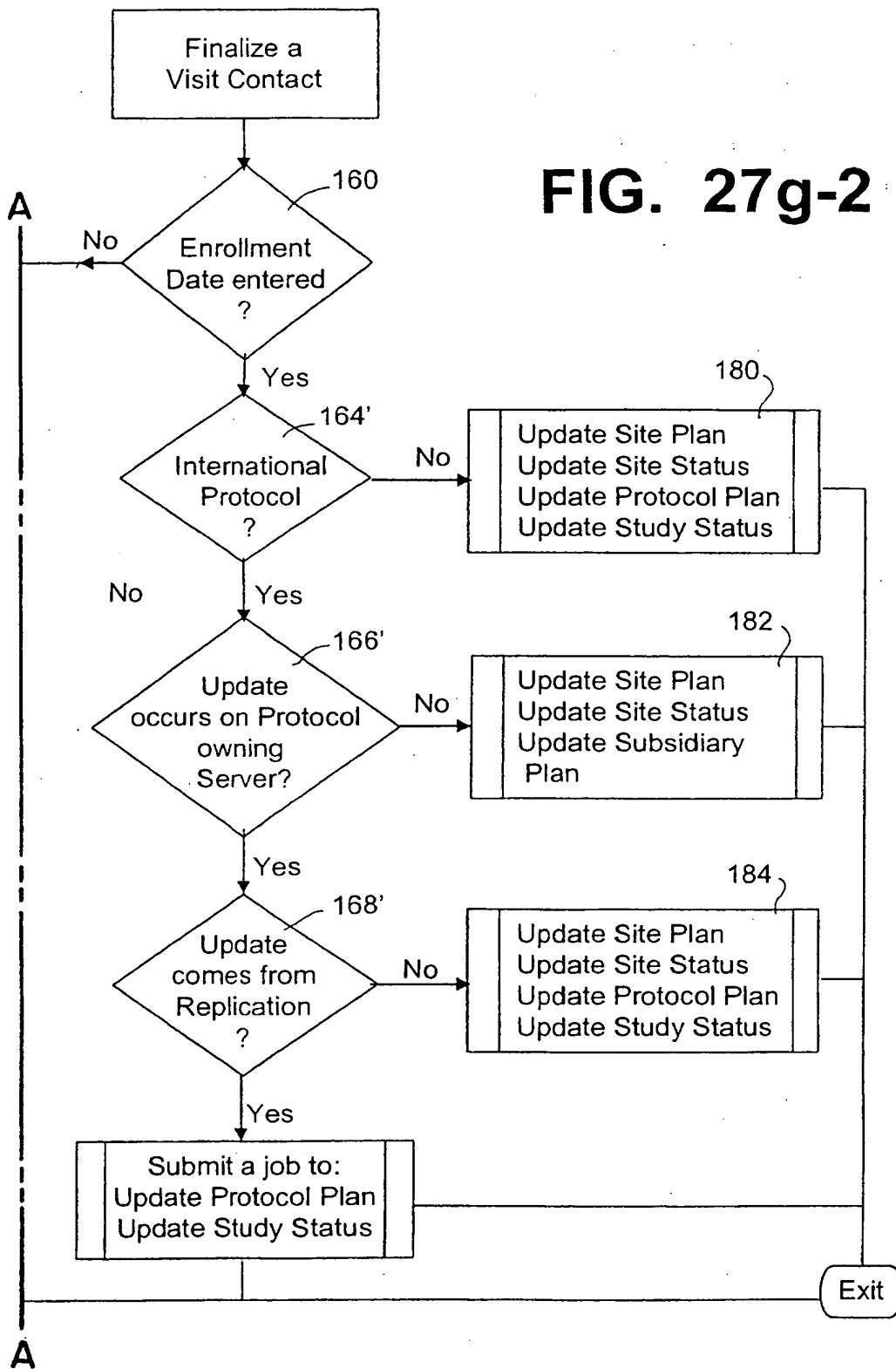
REPLACEMENT SHEET

FIG. 27g-1



REPLACEMENT SHEET

FIG. 27g-2



REPLACEMENT SHEET

FIG. 27h

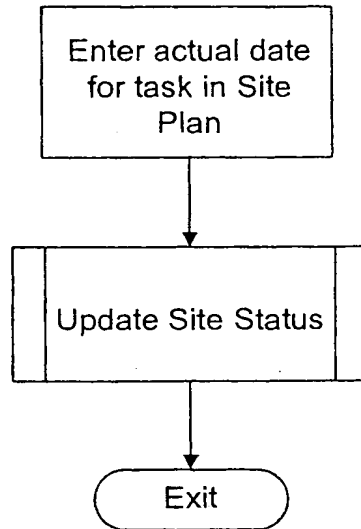
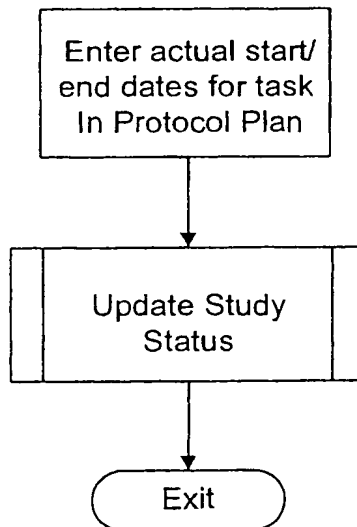


FIG. 27i



REPLACEMENT SHEET

FIG. 28

PROSIT - Never Never Land

Site Number Request									
Request No	Submit Date	Status	Country	Prefix	Protocol	Site	Requester	Investigator	Never Never Land
RQ-10293	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	1	Training, One	Investigator, One	Never Never Land
RQ-10294	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	2	Training, Two	Investigator, Two	Never Never Land
RQ-10295	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	3	Training, Three	Investigator, Three	Never Never Land
RQ-10296	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	4	Training, Four	Investigator, Four	Never Never Land
RQ-10297	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	5	Training, Five	Investigator, Five	Never Never Land
RQ-10298	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	6	Training, Six	Investigator, Six	Never Never Land
RQ-10299	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	7	Training, Seven	Investigator, Seven	Never Never Land
RQ-10300	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	8	Training, Eight	Investigator, Eight	Never Never Land
RQ-10301	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	9	Training, Nine	Investigator, Nine	Never Never Land
RQ-10302	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	10	Training, Ten	Investigator, Ten	Never Never Land
RQ-10303	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	11	Training, Eleven	Investigator, Eleven	Never Never Land
RQ-10304	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	12	Training, Twelve	Investigator, Twelve	Never Never Land
RQ-10305	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	13	Training, Thirteen	Investigator, Thirteen	Never Never Land
RQ-10306	28-MAY-1998	ASSIGNED	Never Never Land	Q	P00036	14	Training, Fourteen	Investigator, Fourteen	Never Never Land
RQ-11047	22-DEC-1998	RETURNED	Never Never Land	Q	P00041		Training, One	Hook, Captain	Never Never Land
RQ-11048	22-DEC-1998	ASSIGNED	Never Never Land	Q	P00041	1	Training, One	Hook, Captain	Never Never Land
RQ-11049	22-DEC-1998	ASSIGNED	Never Never Land	Q	P00041	2	Training, One	Bell, Tinker	Never Never Land
RQ-11050	22-DEC-1998	RETURNED	Never Never Land	Q	P00041		Training, One	Investigator, Eight	Never Never Land
RQ-11067	28-DEC-1998	RETURNED	Never Never Land	B	P00100		Training, One	Bell, Tinker	Never Never Land
RQ-11068	28-DEC-1998	RETURNED	Never Never Land	A	P00102		Training, One	Bell, Tinker	Never Never Land
RQ-11069	28-DEC-1998	RETURNED	Never Never Land	A	P00102		Training, One	Big Chief, Red	Never Never Land
RQ-11070	28-DEC-1998	RETURNED	Never Never Land	A	P00102		Training, One	Bell, Tinker	Never Never Land
RQ-11071	28-DEC-1998	ASSIGNED	Never Never Land	A	P00102	1	Training, One	Bell, Tinker	Never Never Land
RQ-11072	28-DEC-1998	ASSIGNED	Never Never Land	A	P00102	2	Training, One	Big Chief, Red	Never Never Land

FIG. 29

REPLACEMENT SHEET

PROSIT - Never Never Land -- [Site Request Details (New)]		
Request No:		Submit Date:
Protocol:	A-P00102	Status: NEW
Requester:	Training, Six	
Investigator:		
Location:	Never Never Land	
Site Number:		

REPLACEMENT SHEET

PROSIT - UNITED STATES				
Site Administration				
Protocol:	I-P00324	Schering No: 000049	Schering Name: ANTERON	
Site No:	1	Investigator: Abdulhay, G	Country: UNITED STATES	
Site Administration		Post Study Eval.		
Protocol				
Study Status:	PLANNED	Notification:	RESUME STUDY	
Notification Reason:				
Site Status:	PLANNED	Effective Amendment:	1	
Data Collection Tool:	CRF	Effective Date:	04-NOV-1998	
Projected Enrollment		Budget		
Req. Minimum: 0	Site Enrollment: 1	Procedure Level 0 Site Level ●		
Prim. Location: YYY	Pre-Study Visit:	Currency: U.S. DOLLARS		
Name	Function	Phone	Fax	Local Inv. No
Abdulhay, G PRINCIPAL INVESTIGATOR				

FIG. 30

FIG. 31

REPLACEMENT SHEET

PROSIT - UNITED STATES			
Site Administration			
Protocol:	I-P00324	Schering No: 000049	Schering Name: ANTERON
Site No:	1	Investigator: Abdulhay, G	Country: UNITED STATES
Site Administration		Post Study Eval.	
Global Assessment:	NOT RECOMMENDED	Evaluated By: Rispoli, Marc C	
		Evaluated On: 12 -NOV-1998	
ADEQUACY OF PATIENT SOURCE	GOOD	DRUG STORAGE AREA	ADEQUATE
FACILITIES	GOOD	LABORATORY	VERY GOOD
PRINCIPAL/CO-PRINCIPAL INVESTIGATOR	VERY GOOD	PI'S TIME TO CONDUCT/SUPERVISOR	VERY GOOD
STUDY STAFF	VERY GOOD	SUB INVESTIGATOR(S)	VERY GOOD

FIG. 32

PROSIT - UNITED STATES			
Site Personnel & Locations			
Protocol:	I-P00324	Schering No: 000049	Schering Name: ANTERON
Site No:	1	Investigator: Abdulhay, G	Country: UNITED STATES
Locations	SP Personnel	Non SP Personnel	Non SP Personnel Locations
Active	Primary Location	Role	Country Address
<input checked="" type="checkbox"/>	<input type="checkbox"/> HELSINGIN YUOPIST	<input type="checkbox"/> (CO)SPONS	FINLAND KESKUSSAIRAALA MEILAHDENTI
<input checked="" type="checkbox"/>	<input type="checkbox"/> 3V45 HSC MCMASTER	<input type="checkbox"/> CENTRAL IR	CANADA This is address line 1 for external organization printing 123456
<input checked="" type="checkbox"/>	<input type="checkbox"/> 410-2000 CREDIT VALL	<input type="checkbox"/> CONTRACTI	CANADA MISSISSAUGA
<input checked="" type="checkbox"/>	<input type="checkbox"/> SCICOR, INC.	<input type="checkbox"/> CENTRAL IR	UNITED STATES 8211 SCICOR DRIVE
<input checked="" type="checkbox"/>	<input type="checkbox"/> KENILWORTH	<input type="checkbox"/> CENTRAL IR	UNITED STATES ADDRESS
<input checked="" type="checkbox"/>	<input type="checkbox"/> YYYY	<input type="checkbox"/> CENTRAL L	CANADA YYYY
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

FIG. 33

PROSIT - UNITED STATES									
Site Personnel & Locations									
Protocol:		I-P00324	Schering No: 000049		Schering Name: ANTERON				
Site No:		1	Investigator: Abdulhay, G		Country: UNITED STATES				
Locations		SP Personnel	Non SP Personnel	Locations					
Active	Write	Employee	Responsibility		Active Date	Inactive Date	Country	Expense	
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Rispoli, Marc C	SITE REQUESTER		03-NOV-1998	00--0000	USA	RESEARC	
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Lee, J S	Clinical Data Coordi		12-NOV-1998	00--0000	USA	CHEM PR	
<input checked="" type="checkbox"/>	<input type="checkbox"/>				05-JAN-1999	00--0000			

FIG. 34

PROSIT - UNITED STATES

Site Personnel & Locations

Protocol: I-P00324 Schering No: 000049 Schering Name: ANTERON

Site No: 1 Investigator: Abdulhay, G Country: UNITED STATES

Locations SP Personnel Non SP Personnel Non SP Personnel Locations

Active	Person	Responsibility	Active Date	Inactive Date	Country	Phone No.
<input type="checkbox"/>	Aapro, Mary S	Principal Investigator	03-NOV-1998	03-NOV-1998	U.S. VI	908-603-3952
<input checked="" type="checkbox"/>	Aarons-You Ok AL	Data Entry Clerk/Data C	04-NOV-1998	04-NOV-1998	U.S.A.	
<input checked="" type="checkbox"/>	Abdulhay, G	Principal Investigator	04-NOV-1998	04-NOV-1998	U.S.A.	234-243-1234
<input checked="" type="checkbox"/>	Aaronson, AL	Dietician	12-NOV-1998	12-NOV-1998	U.S.A.	
<input checked="" type="checkbox"/>	Aaronson, D	Hospital Administrator	12-NOV-1998	12-NOV-1998	SAMOA	
<input checked="" type="checkbox"/>	656566, 67777 76	Contract/Grant Administr	12-NOV-1998	12-NOV-1998	U.S.A.	1234
<input checked="" type="checkbox"/>	Abbamont, T	IRB Chairman	12-NOV-1998	12-NOV-1998		
<input checked="" type="checkbox"/>			05-JAN-1999	05-JAN-1999		

REPLACEMENT SHEET

FIG. 35

REPLACEMENT SHEET

PROSIT - UNITED STATES				
Site Personnel & Locations				
Protocol:	I-P00324	Schering No: 000049	Schering Name: ANTERON	
Site No:	1	Investigator: Abdulhay, G	Country:	UNITED STATES
Locations	SP Personnel	Non SP Personnel	Non SP Personnel Locations	
Associated Site Personnel	Aaronson, D			

Primary	Location	Role	Country	Address	City
<input type="checkbox"/>	SCICOR, INC.	CENTRAL IRB/EC	USA	8211 SCICOR DRIVE	IND
<input type="checkbox"/>	YYYY	CENTRAL LABORATORY	CAN	YYYY	YY
<input type="checkbox"/>	410-2000 CREDIT VALL	CONTRACT RESEARCH ORG.	CAN	MISSISSAUGA	ON
<input type="checkbox"/>	3V45 HSC MCMASTER	CENTRAL IRB/EC	CAN	This is address line 1 for external organization printing 123456	HAI
<input checked="" type="checkbox"/>	HELSINGIN YUOPISTO	(CO)SPONSORING ORG.	FIN	KESKUSSAIRAALA MEILAHDENTIE2	002
<input type="checkbox"/>	KENILWORTH	CENTRAL IRB/EC	USA	ADDRESS	City
<input type="checkbox"/>					

FIG. 36

PROSIT - UNITED STATES

Site Study Tracking

Protocol: 1-P00324 Schering No: 000049 Schering Name: ANTERON

Country: UNITED STATES Site No: 1 INVESTIGATOR: Abdulhay, G

Seq	Task Name	Latest Date	Actual Date	
1	1P00324- USA	00-000-0000	02-NOV-1998	<input checked="" type="checkbox"/>
2	Completed Grant Request Form Received in Sub.	00-000-0000	00-000-0000	<input checked="" type="checkbox"/>
3	CV of Laboratory Director(s) Received in S	00-000-0000	00-000-0000	<input checked="" type="checkbox"/>
4	Budget Info Sheet (signed & dated by Inv.) Rec.	00-000-0000	00-000-0000	<input checked="" type="checkbox"/>
5	CV of Laboratory Director(s) Received in Sub.	00-000-0000	00-000-0000	<input checked="" type="checkbox"/>
6	CV of Laboratory Director(s) Sent to HQ	00-000-0000	00-000-0000	<input checked="" type="checkbox"/>
7	Completed Grant Request Form Sent to HQ	00-000-0000	00-000-0000	<input checked="" type="checkbox"/>
8	Curriculum Vitae of Principal Inv.(s) Rec. in	00-000-0000	00-000-0000	<input checked="" type="checkbox"/>
9	Curriculum Vitae of Principal Investigators	00-000-0000	00-000-0000	<input checked="" type="checkbox"/>
10	Curriculum Vitae of Sub-Inv.(s) Received in S	00-000-0000	00-000-0000	<input checked="" type="checkbox"/>
11	Curriculum Vitae of Subinvestigator(s) Sent t	00-000-0000	00-000-0000	<input checked="" type="checkbox"/>
12	Doc. Of Quality Control Proc. Or Cert. Rec. in	00-000-0000	00-000-0000	<input checked="" type="checkbox"/>
13	Doc. Of Quality Control Proc. Or Cert. Sent to	00-000-0000	00-000-0000	<input checked="" type="checkbox"/>
14	FDA Form 1572 Received in Sub.	00-000-0000	00-000-0000	<input checked="" type="checkbox"/>
15	FDA Form 1572 Sent to HQ.	00-000-0000	00-000-0000	<input checked="" type="checkbox"/>
16	Gov. Regulatory App. (w/trans.) Sent to HQ.	00-000-0000	00-000-0000	<input checked="" type="checkbox"/>
17	Gov. Regulatory App. (w/trans.) Received in S	00-000-0000	00-000-0000	<input checked="" type="checkbox"/>
18	Informed Consent Task (Trans)	00-000-0000	00-000-0000	<input checked="" type="checkbox"/>
19	Informed Consent Doc. (with translation) Sent	00-000-0000	00-000-0000	<input checked="" type="checkbox"/>
20	Site Closed	00-000-0000	00-000-0000	<input checked="" type="checkbox"/>

REPLACEMENT SHEET

FIG. 37

PROSIT - UNITED STATES			
Site Budget			
Protocol:	<input type="text" value="I-P00324"/>	Schering No: 000049	Schering Name: ANTERON
Site No:	<input type="text" value="1"/>	Investigator : Abdulhay,G.	Currency: U.S. Dollars Revision: <input type="text"/>
Administration	Site Payees	Site Budget	Subject Costs
<div> <div>Status:</div> <div>Amendment:</div> <div>Submit Date: 00--0000</div> <div>Effective Date: 00--0000</div> <div>Overhead Percent: <input type="text" value="0.00"/></div> </div>			

REPLACEMENT SHEET

FIG. 38

PROSIT - UNITED STATES				
Site Budget				
Protocol: I-P00324 Schering No: 000049 Schering Name: ANTERON				
Site No: 1 Investigator : Abdulhay,G. Currency: U.S. Dollars Revision:				
Administration	Site Payees	Site Budget	Subject Costs	
Local Payee Global Payee Finance Code				
		10 th SYMPOSIUM MOLECULAR		

REPLACEMENT SHEET

PROSIT - Never Never land									
Site Budget									
Protocol: <input type="text" value="A-P00102"/>		Schering No: 000001		Schering Name: STEROIDS FOR SKIN TESTS					
Site No: <input type="text" value="4"/>		Investigator: Big Chief, Red		Currency: GOURDE		Revision: <input type="text" value="1"/>			
Administration		Site Payees		Site Budget		Subject Costs			
Protocol: P00102 Site No 4 Revision: 1-IN Revision Effective Date: Amendment:									
Line Item		OH Default Payee		Unit Cost		Units		Total	
SUBJECT COSTS									
PROCEDURE COSTS									
Laboratory Evaluation		<input type="text" value="Captain Hook"/>		<input type="text" value="10.00"/>		<input type="text" value="5"/>		<input type="text" value="50.00"/>	
Medical History		<input checked="" type="checkbox"/>		<input type="text" value="100.00"/>		<input type="text" value="2"/>		<input type="text" value="200.00"/>	
		<input type="checkbox"/>		<input type="text" value=".00"/>					
ADDITIONAL VISIT COSTS									
Evaluation		<input checked="" type="checkbox"/>		<input type="text" value="100.00"/>		<input type="text" value="3"/>		<input type="text" value="300.00"/>	
		<input type="checkbox"/>		<input type="text" value=".00"/>					
ADJUSTMENTS									
Recovery		<input type="checkbox"/>		<input type="text" value="100.00"/>		<input type="text" value="2"/>		<input type="text" value="200.00"/>	
		<input type="checkbox"/>		<input type="text" value=".00"/>					
OTHER COSTS									
Advertisement		<input type="checkbox"/>		<input type="text" value="100.00"/>		<input type="text" value="2"/>		<input type="text" value="200.00"/>	
Discovery		<input type="checkbox"/>		<input type="text" value="20.00"/>		<input type="text" value="3"/>		<input type="text" value="60.00"/>	
TOTAL BUDGET								1,060.00	
PREVIOUSLY APPROVED									
REQUIRED									

FIG. 39

FIG. 40

PROSIT - UNITED STATES				
Site Budget				
Protocol: <input type="text" value="I-P00324"/>		Schering No: 000049 Schering Name: ANTERON		
Site No: <input type="text" value="1"/>		Investigator: Abdulhay, G Currency: U.S. DOLLARS Revision <input type="text"/>		
Administration		Site Payees	Site Budget	Subject Costs
Treatment Schedule: <input type="text" value="Treatment Schedule 1"/>				
Line Item	Visit # > Subjects Budgeted >	1	2	3
<input type="text" value="13C-UREA BREATH TEST"/>		\$.00	\$.00	\$.00
<input type="text" value="12-LEAD ECG"/>		\$.00	\$.00	\$.00
<input type="text" value="2-VIEW XRAY"/>		\$.00	\$.00	\$.00
<input type="text" value="24- HOUR URINE COLLECTION"/>		\$.00	\$.00	\$.00
<input type="text" value="4-VIEW XRAY"/>		\$.00	\$.00	\$.00
<input type="text"/>		\$.00	\$.00	\$.00

REPLACEMENT SHEET

FIG. 41

PROSIT - UNITED STATES				
Pre-Study Visit				
Protocol:	I-P00324	Schering No:	000049	Schering Name: ANTERON
Pre-Study Visit No.:	10566	Principal Investigator:	Abdulhay, G	Country: NORWAY
Pre-Study Visit	SP Personnel	NSP Personnel	Discussion Items	Evaluation
Potential Investigator:	Aasebo, U	Potential Investigator:	Location Name	
Country:	AFGHANISTAN			
Visit Date:	18-NOV-1998	Time:	16:25	Finalized: 00--0000
Schering Participants:		Investigator Site Participants: Non-Registered ()		
Rispoli, Marc C		Aasebo, U		

FIG. 42

PROSIT – UNITED STATES				
Pre-Study Visit				
Protocol: I-P00324 Schering No: 000049 Schering Name: ANTERON				
Pre-Study Visit No.: 10566 Principal Investigator: Abdulhay, G Country: NORWAY				
Pre-Study Visit	SP Personnel	NSP Personnel	Discussion Items	Evaluation
Registered Site Personnel Title				
Aasebo, U				
Non-Registered Site Personnel				
Last Name First Name Title				

FIG. 43

PROSIT - UNITED STATES			
Pre-Study Visit			
Protocol:	I-P00324	Schering No: 000049	Schering Name: ANTERON
Pre-Study Visit No.	10566	Principal Investigator: Aasebo, U	Country: NORWAY
Pre-Study Visit	SP Personnel	NSP Personnel	Discussion Items
STUDY CONSIDERATIONS		ETHICAL CONSIDERATIONS	
<input checked="" type="checkbox"/> Pre Clinical Data <input checked="" type="checkbox"/> Clinical Data <input checked="" type="checkbox"/> Investigator Brochure <input checked="" type="checkbox"/> Protocol <input checked="" type="checkbox"/> Case Report Forms <input checked="" type="checkbox"/> Monitoring Responsibilities <input checked="" type="checkbox"/> Study Schedule <input checked="" type="checkbox"/> Principal Investigator Responsibilities <input checked="" type="checkbox"/> Sub-Investigator Responsibilities <input checked="" type="checkbox"/> Staff Responsibilities <input checked="" type="checkbox"/> Grant <input checked="" type="checkbox"/> Payment Schedule	<input checked="" type="checkbox"/> Curriculum Vitae <input checked="" type="checkbox"/> Principal Investigator <input checked="" type="checkbox"/> Co-Principal Investigator <input checked="" type="checkbox"/> Sub-Investigator <input checked="" type="checkbox"/> Lab Director <input checked="" type="checkbox"/> Laboratory Certification <input checked="" type="checkbox"/> Laboratory Q.C. Procedures <input checked="" type="checkbox"/> Laboratory Reference Ranges <input checked="" type="checkbox"/> DEA Regulations and Drug Control <input checked="" type="checkbox"/> Adequacy and Accuracy of Records <input checked="" type="checkbox"/> Availability of Patient Records <input checked="" type="checkbox"/> Drug Accountability and Disposition	<input checked="" type="checkbox"/> IRB/EC <input checked="" type="checkbox"/> Approval Documents <input checked="" type="checkbox"/> Responsibilities <input checked="" type="checkbox"/> Retention of Records <input checked="" type="checkbox"/> Informed Consent <input checked="" type="checkbox"/> FDA 1572 OR <input checked="" type="checkbox"/> Investigator Agreement <input checked="" type="checkbox"/> Nature of FDA Inspection	

FIG. 44

PROSIT - UNITED STATES			
Pre-Study Visit			
Protocol:	I-P00324	Schering No:	000049
Pre-Study		Schering Name:	ANTERON
Visit No.	10566	Principal Investigator:	Aasebo, U
		Country:	NORWAY
Pre-Study Visit	SP Personnel	NSP Personnel	Discussion Items
			Evaluation
Global Assessment:			
RECOMMENDED		<input checked="" type="checkbox"/>	
ADEQUACY OF PATIENT SOURCE		GOOD	
FACILITIES			
PRINCIPAL INVESTIGATOR / PRINCIPAL			
STUDY STAFF			
DRUG STORAGE AREA			
LABORATORY			
PI'S TIME TO CONDUCT/SUPERVISE		VERY GOOD	
SUB INVESTIGATORS			

REPLACEMENT SHEET

FIG. 45

PROSIT - United States	
Visit Contact	
Protocol: I-P00324	Schering No: 000049 Schering Name: ANTERON
Site No: 1	Contact: 00011286 - 04 - Nov -1998 unfinalized
Visit Contact	Discussion Items
Contact Information	
Originator: Rispoli, Marc C	Reason: CLINICAL STUDY SUPPLIES
Date: 04-Nov-1998	Time: 00:00
Meeting Location	
Site Roster: testing the new prosit 1.03.1 build	
Other:	
Recommendation	
The investigator site is: Recommended: <input checked="" type="checkbox"/> Not Recommended: <input type="checkbox"/>	
Schering Participants	
Rispoli, Marc C	
Non-Schering Participants	
Apro, Mary S	

FIG. 46

PROSIT – Never Never Land			
Electronic Mail Contact			
Protocol: Q-P000036		Schering No: 032088	
Site No: 4		Schering Name: MOMETASONE	
		Contact: 00008480 – 02-Aug-1999 unfinalized	
Electronic Mail Contact		Discussion Items	
Contact Information			
Originator: Darling, John		Reason: ADVERSE EVENT	
Date: 02-Aug-1999		Time: 05:01	
Phone Contact Details			
Outside Party Phone #:		555-555-5555	
Schering Participants		Non-Schering Participants	
Butt, Thud			

FIG. 47

PROSIT – United States

Visit Contact

Protocol:

Schering No: 000049

Schering Name: ANTERON

Site No:

Contact:

Visit Contact | Discussion Items

New Pre-Clinical or Clinical Data

- ☐ Efficacy
- ☐ Adverse Events

Protocol Adherence

- ☐ Subject Selection
- ☐ Conduct of Study
- ☐ Adverse Events
- ☐ Concomitant Medications

Case Report Form (CRF) Records

- ☐ CRF Completion vs. Patient Enrollment
- ☐ CRF Completeness
- ☐ CRF Availability, Storage and Retention

Personnel Responsibilities

- ☐ Principal Investigator
- ☐ Sub-Investigator
- ☐ Staff

Facilities

- ☐ Location of Patient Info.
- ☐ Clinical Laboratory
- ☐ Equipment
- ☐ Other

Clinical Supplies

- ☐ Quantity
- ☐ Storage
- ☐ Dispensing
- ☐ Packaging/Labeling/Coding
- ☐ Randomization
- ☐ Recertification Date
- ☐ Drug Disclosure Envelopes
- ☐ Documentation of Accountability

Monitoring Activities

- * ☐ Action taken by P1 and Monitor to correct deficiency
- * ☐ Source Document Verification Completed
- * ☐ Consents Reviewed
- * ☐ Source Document Checked

* Required to finalize the site contact

REPLACEMENT SHEET

FIG. 48a

PROSIT – UNITED STATES

Site Tracking

Protocol:

I-P00324

Schering No: 000049

Schering Name: ANTERON

Site:

1

Contact: 11286 Visit Unfinalized

As of:

04-Nov-1998

Enrollment Tracking

Ineligible For Screening

Potential Subjects Ineligible for Screening:

2

Enrollment as
of Unfinalized
Site Visit

Enrollment as
of Finalized
Visit

Number of Subjects Screened:

10

1

0

Number of Subjects Failed Screening:

2

0

0

Number of Subjects Enrolled:

8

1

0

Number of Subjects Discontinued Total:

2

0

0

Adverse Events:

1

0

0

Other:

1

0

0

Number of Subjects Complete:

5

0

0

Number of Subjects Ongoing:

1

0

0

REPLACEMENT SHEET

REPLACEMENT SHEET

PROSIT – Never Never Land			
Site Tracking			
Protocol:	<input type="text" value="000065"/>	Schering No: 032088	Schering Name: MOMETASONE
Site:	<input type="text" value="1"/>	Contact: 2856 Telephone Unfinalized	As of: <input type="text" value="30-Mar-1998"/>
Enrollment Tracking		Ineligible For Screening	
		Number of Subjects as of 30-Mar-98	Percent of Site Total
Site Total:		<input type="text" value="1"/>	
Reason For Ineligibility			
PREGNANCY		<input type="text" value="1"/>	<input type="text" value="100.0"/>
EXCLUDED CONCOMITANT MEDICATION		<input type="text" value="0"/>	<input type="text" value="0.0"/>
DISEASE IS TOO SEVERE		<input type="text" value="1"/>	<input type="text" value="100.0"/>

FIG. 48b

FIG. 49

REPLACEMENT SHEET

PROSIT - UNITED STATES			
Subject Visit Tracking			
Protocol: I-P00324	Site No: 1	Contact: 11286	
Screening Number: 1	Subject Number: 3	Initials:	
Subject	Visit Summary	Discount	Unsched 2 1
Gender: MALE	Date of Birth: 01-Jan-1971	Age: 27	Enrollment: 27 Years
Signed Consent: 02-Nov-1998	Last Visit Number: 0	Discontinuation Visit	
Enrollment: 09-Nov-1998	Current Phase: MAINTENANCE		
Therapy Started: 00--0000	Complete: <input type="checkbox"/>	Useable/Evaluable: <input type="checkbox"/>	
Therapy Ended: 00--0000	Reason For Discontinuation:		
Days On Therapy:	Discontinuation Date: 30-Nov-1998		
Additional Subject Date:			
SUBJECT 1:			

FIG. 50

PROSIT - UNITED STATES									
Subject Visit Tracking									
Protocol: I-P00324		Site No: 1		Contact: 11286					
Screening Number: 1		<input type="checkbox"/>		Subject Number: 3		Initials: <input type="text"/>			
Subject		Visit Summary		Discount		Unsched		2 1	
Visit No	Amendment	Visit Label	Visit Date	Delta	To Do	CRF Status	SDV Status		
1		Visit 1	09-Nov-1998		<input type="checkbox"/>	COLLECTED	<100%		
2		Visit 2	16-Nov-1998	6	<input type="checkbox"/>	PARTIALLY COLLECTED	<100%		
3		Unscheduled Visit	23-Nov-1998		<input checked="" type="checkbox"/>	PARTIALLY COLLECTED			
4		Discontinued Visit	30-Nov-1998		<input checked="" type="checkbox"/>	NOT COLLECTED			

Ready

05-Jan-1999

REPLACEMENT SHEET

FIG. 51

PROSIT - UNITED STATES	
Formulated Materials Requisition	
FMR Req. ID: 184	
Administration	Materials
Protocol Information	
Protocol Number: A-P00240	Schering No: 000028 A AND D
Program Code: F05	Schering No: 000028
Expense Center: 1495-WORLDWIDE RSCH QA	Marketed
Requisition Source: ANIMAL HEALTH DOMESTIC/INTERNATIONAL	Dose Form: Bolus
Requested by: Desontos, Marc	
Authorized by: Desontos, Marc	
Date Required For Packaging: 22-Dec-1998	Binding Required: <input type="checkbox"/>
Special Directions and Binding (explain binding requirements if any):	

REPLACEMENT SHEET

FIG. 52

REPLACEMENT SHEET

PROSIT - UNITED STATES			
PSR Request: Protocol Packaging			
Protocol: I-P00324	Schering No: 000049	Schering Name: ANTERON	
Country: UNITED STATES	PSR No: 1489		
PSR Information Components Ship To			
Project Accounting Code: FO1 - 000049 - 303E		Exp Center: 1477 RESEARCH SYS	
Special Instructions: <input checked="" type="checkbox"/>			
New Protocol / Site: <input type="checkbox"/>	Study Type: <input type="radio"/> Blind <input type="radio"/> Open	Attachments: <input checked="" type="checkbox"/>	
Study Monitor: Grint, P C	Random Code Format: CODE ENVELOPES	PROTOCOL: <input type="checkbox"/>	
Requested by: Rispoli, Marc C	Authorized by: 3,3	LABEL FORMAT: <input type="checkbox"/>	
Required Ship Date: 31-Mar-1999	IND Labeling Date: 00-0000	LABELING INSTRUCTIONS: <input type="checkbox"/>	
		DEA FORM 222C: <input type="checkbox"/>	
		CONFIRMATION DEA REG: <input type="checkbox"/>	
Random Code	Generation ID:	Select Sites:	<input type="checkbox"/>

FIG. 53

PROSIT - UNITED STATES					
PSR Request: Protocol Packaging					
Protocol: C-C98005		Schering No: 032088		Schering Name: MOMETASONE	
Country: UNITED STATES		PSR No 1606			
PSR Information Components Ship To					
Schering No:	Schering Name	Test Dose Form	Strength/Concentration	Package Description	Required Units
032088	MOMETASONE	ORAL AERPR	UNKNOWN		

FIG. 54

PROSIT - UNITED STATES	
PSR Request: Protocol Packaging	
Protocol: I-P00324	Schering No: 000049
Schering Name: ANTERON	
Country: UNITED STATES	PSR No 1489
PSR Information Components Ship To	
Location: SCHERING CANADA INC.	
Address: 170 ONEIDA STREET	
City: POINTE CLAIRE	US State / Other:
Postal Code: H9R 1B4	Country: CANADA
Phone:	Fax: 514 426 7300
Attention:	

REPLACEMENT SHEET

FIG. 55

PROSIT -- UNITED STATES									
Material Transfer Request									
Protocol:		C-P98615		Schering No: 034117		Schering Name: DESLORATADINE			
Country:		UNITED STATES		Site No: 1		MTR No:			
MTR Details		Ship To							
Inventory Location:						Requested Ship Date: 00--0000			
Requested By:		Caprio, Denise M							
Authorized By:									
Expense Center:		1751 SR DIR INTL CLIN RES				Intended Use Of Material: <input checked="" type="checkbox"/>			
Material Type		Batch No.		PSR No.		FMR No.		Quantity On Hand	
<input type="text"/>		<input type="text"/>		<input type="text"/>		<input type="text"/>		<input type="text"/>	

FIG. 56

PROSIT - UNITED STATES	
Material Transfer Request	
Protocol: C-P98615	Schering No: 034117
Schering Name: DESLORATADINE	
Country: UNITED STATES	Site No: 1
MTR No: AA000637	
MTR Details	Ship To
Location:	
Address:	
City:	State/Province:
Postal Code:	Country:
Phone:	Fax:
Attention:	
Shipping/Packaging Instructions:	

REPLACEMENT SHEET

FIG. 57

PROSIT – UNITED STATES			
Random Code Request - New			
Protocol: Q-P00759	Schering No: 032088 Schering Name: MOMETASONE		
Random Code Req ID: 	Date Prepared: 00- -0000	Pctl Finalization Date: 21-Jul-1999	
To: 	Copies: 		
From: Caprio, Denise, M			
Random Code Type: 			
Generate Random Code by: 00- -0000			
Number of United States Sites: 2	Random Code Generation ID: 		
Number of International Sites: 	First United States Site ID: 1	Comments: 	
First International Site ID: 1	<input checked="" type="checkbox"/>		
Subjects Randomized by: 			
Subjects Replaced by: 	Treatment Arm Subjects 		
Subject nbr assigned by: 			
Number of Stratification: 	Total Subjects: 0		

REPLACEMENT SHEET

FIG. 58

REPLACEMENT SHEET

PROSIT - United States				
Check Control				
Unsend: <input type="text" value="RENOWSKIG"/>		<input type="text" value="Renowski, George"/>		
Check Out				
Date: 13-Jul-1999		Extra Items <input type="checkbox"/>		Status: Checked out data available
Protocol	Site	Primary Location	Site Investigator	Site Requestor
B93214	<input type="text"/>	No Site - Ptcl only		
B94055	<input type="text"/>	No Site - Ptcl only		
B94056	<input type="text"/>	No Site - Ptcl only		
Request Date	Status	Check In Date	Checked In Date	Reply from Server

FIG. 61

PROSIT - Never Never Land

Site / Subject Summary Report

PROSIT - SITE / SUBJECT SUMMARY REPORT

Schering No.	032088 MOMETASONE	Working Study Title	MOMETASONE VS. Budesonide in Aithsma	Protocol No.-Site No.	0000033-1
Principal Investigator	J G ORTIZ	Study Location	ENGELWOOD, CO, UNITED STATES	Monitor	

Site 1 Details

Site Status: ENROLLMENT ONGOING # Subjects Projected: Data Collection Tool: CRF

Enrollment Summary	Site Level	Subj. Level	Milestones	Monitoring Summary	CRF
# Subj. Ineligible for Screening:	0	2	Site Initiation Visit Date:	Total Visits Completed:	6
# Subj. Screened:	0	0	First Subject Screened:	Visits Monitored:	4 (66%)
# Subj. Failed Screening:	0	0	First Subject Enrolled:	Visits 100% SDV:	1 (16%)
# Subj. Enrolled (% Projected)	0	2	Last Subj. Enrolled to Date:	Visits Collected:	4 (66%)
# Subj. Ongoing:	0	1	Enrollment Complete:	Date of Last Contact:	25-MAR-1998
# Subj. Discontinued:	0	0	Last Subject Last Visit:	Date of Last Visit:	25-MAR-1998
# Subj. Complete:	0	1	Close Out Visit:	Visits at the Site:	1

Per Subject Summary

Subject ID	Age	Gender	Date Enrolled	Status	Last Visit (phase)	Last Visit Date	Reason for Discontinuation	Eval Started	Date RX Stopped
------------	-----	--------	---------------	--------	--------------------	-----------------	----------------------------	--------------	-----------------

600 1DL 1 25 years M O t1v1 04-FEB-1998 UN

Start	Microsoft Word Report	PROSIT - Never Ne...	2.00PM
-------	-----------------------	----------------------	--------

FIG. 62

PROSIT – Never Never Land

Monitoring Status Report

PROSIT – MONITORING STATUS REPORT

Schering No.	032088 MOMETASONE	Working Title	MOMETASONE VS. Budesonide in Asthma	Protocol No.-Site No.	0000000-1
Principal Investigator	J G ORTIZ	Study Location	ENGELWOOD, CO, UNITED STATES	Monitor	

Site 1 Summary

As Of 25-MAR-1998

Site Contact No: 2626

	Amended Enrollment Ongoing	Completed Monitored 100% SDV Collected	Visits 6 4 1 4 (88%) (18%) (88%)	Subjects Projected: Actual # Screened: Actual # Cancelled: Actual # Completed:
Protocol:				2
Site:				1
Visits at the Site:	4			1
Date of Last Visit:	25-MAR-1998			

Site 1 Details Subject	V1	V2	V3	V4	V5	V6	V7	V8	V8	V9	V10	V11	V12	V13	V14	V15
600WDV1	(100)	(k)	(k)	(100)												
7ICR18007																
Completed	2	1	1	1	0	0	1	0	0	0	0	0	0	0	0	0
Monitored	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0
Collected	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0

Legend: C= Completed; 100=100%; SDV= Collected; xxxxx = D xxxxxxxx
V1 - xxxxxx V2 - xxxxxx V4 xxxxxx

FIG. 63

PROSIT -- Never Never Land			
Site Personnel & Locations Information Report			
PROSIT -- SITE PERSONNEL & LOCATIONS INFORMATION SHEET			
Schering No.	032066 MOMETASONE	Working Title	Mom vs. Bud in Asthma
Protocol No.	AP00045-1	Expense Center	1763--CLINICAL RESEARCH--ALLERGY II
Principal Investigator	J TABAS COMINGUILLAN	Monitoring Country	Never Never Land
NON SP PERSONNEL			
Maid, Mer	Tabascominguillan, J	Bell, Tinker	
IRB CHAIRMAN	Principal Investigator	STUDY COORDINATOR	
NNL	NNL	NNL	
Active: 22-Apr-1998	Active: 22-Apr-1998	Active: 22-Apr-1998	
CENTRAL IRB/EC			
MERMAID ROCK			
2 Stone Skip			
NNL			
TREATMENT CENTER			
PIRATE SHIP			
Out at Sea			
Ready			
6/18/98 14:07:04			

PROSIT - UNITED STATES

Contact Information Report

PROSIT - CONTACT INFORMATION SHEET

Schering No.	000058 NIACIN	Working Title	domestic
Protocol No.	A000001		

PROTOCOL A000001 EXTERNAL ORGANIZATIONS

CENTRE UNIVERSITAIRE DE SANTE #1200

Gunn, Mark C Aarons, A L

DE L LESTRIE 3001 12E AVENUE

Voice: 97

Fax: Voice:

Quebec NORD FAXCAN

SHERBROOKE, QUE

Site: 1

SP PERSONNEL

Manchester London UK

National Genetics Institute

Kadman, D

5839 Green Valley Circle # 104

FAX: 1-310-996-6610

FAX: 1-310-996-6610

Culver City USA

Grint, P C

DSS Specialist

II-10 IN 10D/HIV

USA

Active: 26-Feb-1998

Rispoli, Marc C

PROJECT PHYSICIAN

KEY PRODUCT MGMT.

USA

www.tester.com

Active: 26-Feb-1998

Gunn, Mark C

SITE REQUESTOR

WORLDWIDE RSCH QA

USA

Ready

2/26/98 9:52:37

FIG. 64

REPLACEMENT SHEET

FIG. 65

PROSIT - Never Never Land			
File	Edit	Actions/Modules	Forms Window Help
		EDT Form 1578	
		Investigator Assessment	
		Investigator Report	
		Investigator Request	
Pre-Study Visit		Pre-Study Investigator Visit	
Protocol: 000065		Investigator Formalization Form	
Pre-Study Visit No.: 2867		EMP Form	
		Formulated Materials Request	
		Packaging/Shipement Request Form	
		Material Order Request Form	
Pre-Study Visit		Evaluation	
Country: Never Never Land		Country: Never Never Land	
Visit Date: 31-Mar-1998		Time: 11:00	
		Finalized: 00-0000	
Schering Participants: Investigator Site Participants: Non-Registered ()			
Pan, Peter J		Deck, Hanz	
Butt, Thud		Hook, Captain	
		Smee, Mister	

REPLACEMENT SHEET